A Study to Evaluate the Safety and Antiretroviral Activity of MK-0518 Versus Efavirenz in Treatment Naive HIV-Infected Patients, Each in Combination With TRUVADA (0518-021 EXT)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00369941

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History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

This study will investigate the safety and efficacy of MK-0518 versus efavirenz, in combination with TRUVADA, as a therapy for Human Immunodeficiency Virus (HIV)-infected patients not previously treated.

Condition	Intervention	Phase
HIV Infections	Drug: MK-0518 Drug: Comparator: efavirenz Drug: Comparator: Truvada Drug: Comparator: Placebo to MK-0518 Drug: Comparator: Placebo to efavirenz	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Multicenter, Double-Blind, Randomized, Active-Controlled Study to Evaluate the Safety and Antiretroviral Activity of MK-0518 Versus Efavirenz in Treatment Naive HIV-Infected Patients, Each in Combination With TRUVADA™

Resource links provided by NLM:

MedlinePlus related topics: HIV/AIDS

Drug Information available for: Emtricitabine Tenofovir Efavirenz Tenofovir Disoproxil Fumarate Raltegravir Truvada Raltegravir potassium

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Number of Participants Who Achieved Human Immunodeficiency Virus (HIV) Ribonucleic Acid (RNA) <50 Copies/mL at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: No]

  Antiretroviral activity was evaluated for participants who achieved HIV RNA level <50 copies/mL at Week 48.

- Number of Participants With Clinical Adverse Experiences (CAEs) at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  An adverse experience (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.

- Number of Participants With Serious CAEs at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.

- Number of Participants With Drug-related CAEs at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Serious Drug-related CAEs at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants That Died by Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  All participant deaths in the span of 48 weeks on study were recorded.

- Number of Participants That Discontinued With CAEs at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  An adverse experience (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.

- Number of Participants That Discontinued With Serious CAEs at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.

- Number of Participants That Discontinued With Drug-related CAEs at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants That Discontinued With Serious Drug-related CAEs at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Laboratory Adverse Experiences (LAEs) at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.

- Number of Participants With Serious LAEs at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.

- Number of Participants With Drug-related LAEs at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Serious Drug-related LAEs at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants Discontinued With LAEs at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.

- Number of Participants Discontinued With Drug-related LAEs at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse events (AEs) in this study were defined as "drug-related" if the investigator considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone.

Secondary Outcome Measures:

- Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 48 [Time Frame: 48 Weeks] [Designated as safety issue: No]

  Antiretroviral activity was evaluated for participants who achieved HIV RNA level <400 copies/mL at Week 48.

- Change From Baseline in Cluster of Differentiation Antigen 4 (CD4) Cell Count at Week 48 [Time Frame: Baseline and Week 48] [Designated as safety issue: No]

  Mean change from baseline at Week 48 in CD4 cell count (cells/mm3)

- Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: No]

  Antiretroviral activity was evaluated for participants who achieved HIV RNA level <50 copies/mL at Week 96.

- Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: No]

  Antiretroviral activity was evaluated for participants who achieved HIV RNA level <400 copies/mL at Week 96.

- Change From Baseline in CD4 Cell Count at Week 96 [Time Frame: Baseline and Week 96] [Designated as safety issue: No]

  Mean change from baseline at Week 96 in CD4 cell count (cells/mm3)

- Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: No]

  Antiretroviral activity was evaluated for participants who achieved HIV RNA level <50 copies/mL at Week 156.

- Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: No]

  Antiretroviral activity was evaluated for participants who achieved HIV RNA level <400 copies/mL at Week 156.

- Change From Baseline in CD4 Cell Count at Week 156 [Time Frame: Baseline and Week 156] [Designated as safety issue: No]

Mean change from baseline at Week 156 in CD4 cell count (cells/mm3)

- Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: No]

  Antiretroviral activity was evaluated for participants who achieved HIV RNA level <50 copies/mL at Week 240.

- Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: No]

  Antiretroviral activity was evaluated for participants who achieved HIV RNA level <400 copies/mL at Week 240.

- Change From Baseline in CD4 Cell Count at Week 240 [Time Frame: Baseline and Week 240] [Designated as safety issue: No]

  Mean change from baseline at Week 240 in CD4 cell count (cells/mm3)

- Number of Participants With Nervous System Symptoms Assessed by Review of Accumulated Safety Data up to Week 8 [Time Frame: 8 Weeks] [Designated as safety issue: Yes]

  Participants with dizziness, insomnia, somnolence, concentration impaired, depression, nightmare, confusional state, suicidal ideation, nervous system disorder, psychotic disorder, abnormal dreams, suicide attempt, acute psychosis, delirium, depressed level of consciousness, hallucination, auditory hallucination, completed suicide, and major depression

- Number of Participants With CAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.

- Number of Participants With CAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.

- Number of Participants With CAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.

- Number of Participants With Serious CAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.

- Number of Participants With Serious CAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.

- Number of Participants With Serious CAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.

- Number of Participants With Drug-related CAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Drug-related CAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Drug-related CAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Serious Drug-related CAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Serious Drug-related CAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Serious Drug-related CAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants That Died by Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  All participant deaths in the span of 96 weeks on study were recorded.

- Number of Participants That Died by Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  All participant deaths in the span of 156 weeks on study were recorded.

- Number of Participants That Died by Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  All participant deaths in the span of 240 weeks on study were recorded.

- Number of Participants That Discontinued With CAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.

- Number of Participants That Discontinued With CAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.

- Number of Participants That Discontinued With CAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.

- Number of Participants That Discontinued With Drug-related CAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants That Discontinued With Drug-related CAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants That Discontinued With Drug-related CAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants That Discontinued With Serious CAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.

- Number of Participants That Discontinued With Serious CAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.

- Number of Participants That Discontinued With Serious CAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.

- Number of Participants That Discontinued With Serious Drug-related CAEs at Week 96 [Time Frame: 96 Weeks]
  [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants That Discontinued With Serious Drug-related CAEs at Week 156 [Time Frame: 156 Weeks]
  [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants That Discontinued With Serious Drug-related CAEs at Week 240 [Time Frame: 240 Weeks]
  [Designated as safety issue: Yes]

  Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With LAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.

- Number of Participants With LAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.

- Number of Participants With LAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.

- Number of Participants With Drug-related LAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Drug-related LAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Drug-related LAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Serious LAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.

- Number of Participants With Serious LAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.

- Number of Participants With Serious LAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.

- Number of Participants With Serious Drug-related LAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Serious Drug-related LAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants With Serious Drug-related LAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants Discontinued With LAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.

- Number of Participants Discontinued With LAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.

- Number of Participants Discontinued With LAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.

- Number of Participants Discontinued With Drug-related LAEs at Week 96 [Time Frame: 96 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants Discontinued With Drug-related LAEs at Week 156 [Time Frame: 156 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

- Number of Participants Discontinued With Drug-related LAEs at Week 240 [Time Frame: 240 Weeks] [Designated as safety issue: Yes]

  A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.

Enrollment:	566
Study Start Date:	August 2006
Study Completion Date:	February 2012
Primary Completion Date:	May 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MK-0518 400 mg b.i.d. MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.	Drug: MK-0518 400 mg MK-0518 tablet taken by mouth (PO) twice a day (b.i.d.) for up to 240 weeks Other Names: • raltegravir • Isentress® Drug: Comparator: Truvada One tablet Truvada once a day (q.d.) for up to 240 weeks (one tablet contains 200 mg emtricitabine and 300 mg tenofovir) Other Name: emtricitabine/tenofovir

	disoproxil fumarate Drug: Comparator: Placebo to efavirenz Placebo to efavirenz PO every night (q.h.s.), taken for up to 240 weeks
Active Comparator: Efavirenz 600 mg q.h.s. Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.	Drug: Comparator: efavirenz 600 mg efavirenz tablet taken by mouth (PO) every night (q.h.s.) for up to 240 weeks Other Name: Sustiva® Drug: Comparator: Truvada One tablet Truvada once a day (q.d.) for up to 240 weeks (one tablet contains 200 mg emtricitabine and 300 mg tenofovir) Other Name: emtricitabine/tenofovir disoproxil fumarate Drug: Comparator: Placebo to MK-0518 Placebo to MK-0518 PO b.i.d., taken for up to 240 weeks

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Participant is a male or female at least 18 years of age
- Participant is HIV positive
- Participant is naïve to antiretroviral therapy (ART) and has not received any ART

Exclusion Criteria:

- Participant has received approved or experimental antiretroviral agents in the past
- Participant has been treated for a viral infection other than HIV such as hepatitis B virus infection with an agent that is active against HIV including but not limited to adefovir or lamivudine (= 7 days total)
- Participant has documented resistance to tenofovir, emtricitabine, and/or efavirenz
- Participant has used another experimental HIV-integrase inhibitor
- Participant has a current (active) diagnosis of acute hepatitis due to any cause
- Participants with chronic hepatitis including chronic hepatitis B and/or C may enter the study as long as they have stable liver function tests

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general

information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00369941

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Lennox JL, DeJesus E, Lazzarin A, Pollard RB, Madruga JV, Berger DS, Zhao J, Xu X, Williams-Diaz A, Rodgers AJ, Barnard RJ, Miller MD, DiNubile MJ, Nguyen BY, Leavitt R, Sklar P; STARTMRK investigators. Safety and efficacy of raltegravir-based versus efavirenz-based combination therapy in treatment-naive patients with HIV-1 infection: a multicentre, double-blind randomised controlled trial. Lancet. 2009 Sep 5;374(9692):796-806. doi: 10.1016/S0140-6736(09)60918-1. Epub 2009 Aug 3. Erratum in: Lancet. 2009 Dec 19-2010 Jan 1;374(9707):2054. Lancet. 2009 Sep 5;374(9692):786.

DeJesus E, Rockstroh JK, Lennox JL, Saag MS, Lazzarin A, Zhao J, Wan H, Rodgers AJ, Walker ML, Miller M, DiNubile MJ, Nguyen BY, Teppler H, Leavitt R, Sklar P; STARTMRK Investigators. Efficacy of raltegravir versus efavirenz when combined with tenofovir/emtricitabine in treatment-naïve HIV-1-infected patients: week-192 overall and subgroup analyses from STARTMRK. HIV Clin Trials. 2012 Jul-Aug;13(4):228-32. doi: 10.1310/hct1304-228. Erratum in: HIV Clin Trials. 2012 Sep-Oct;13(5):preceding 233.

Rockstroh JK, Lennox JL, Dejesus E, Saag MS, Lazzarin A, Wan H, Walker ML, Xu X, Zhao J, Teppler H, Dinubile MJ, Rodgers AJ, Nguyen BY, Leavitt R, Sklar P; STARTMRK Investigators. Long-term treatment with raltegravir or efavirenz combined with tenofovir/emtricitabine for treatment-naive human immunodeficiency virus-1-infected patients: 156-week results from STARTMRK. Clin Infect Dis. 2011 Oct;53(8):807-16. doi: 10.1093/cid/cir510.

Rockstroh J, Teppler H, Zhao J, Sklar P, Harvey C, Strohmaier K, Leavitt R, Nguyen BY. Safety and efficacy of raltegravir in patients with HIV-1 and hepatitis B and/or C virus coinfection. HIV Med. 2012 Feb;13(2):127-31. doi: 10.1111/j.1468-1293.2011.00933.x. Epub 2011 May 22.

Rockstroh JK, Teppler H, Zhao J, Sklar P, Miller MD, Harvey CM, Strohmaier KM, Leavitt RY, Nguyen BY. Clinical efficacy of raltegravir against B and non-B subtype HIV-1 in phase III clinical studies. AIDS. 2011 Jul 17;25(11):1365-9. doi: 10.1097/QAD.0b013e328348065a.

Nguyen BY, Isaacs RD, Teppler H, Leavitt RY, Sklar P, Iwamoto M, Wenning LA, Miller MD, Chen J, Kemp R, Xu W, Fromtling RA, Vacca JP, Young SD, Rowley M, Lower MW, Gottesdiener KM, Hazuda DJ. Raltegravir: the first HIV-1 integrase strand transfer inhibitor in the HIV armamentarium. Ann N Y Acad Sci. 2011 Mar;1222:83-9. doi: 10.1111/j.1749-6632.2011.05972.x. Review.

Teppler H, Brown DD, Leavitt RY, Sklar P, Wan H, Xu X, Lievano F, Lehman HP, Mast TC, Nguyen BY. Long-term safety from the raltegravir clinical development program. Curr HIV Res. 2011 Jan;9(1):40-53.

Lennox JL, Dejesus E, Berger DS, Lazzarin A, Pollard RB, Ramalho Madruga JV, Zhao J, Wan H, Gilbert CL, Teppler H, Rodgers AJ, Barnard RJ, Miller MD, Dinubile MJ, Nguyen BY, Leavitt R, Sklar P; STARTMRK Investigators. Raltegravir versus Efavirenz regimens in treatment-naive HIV-1-infected patients: 96-week efficacy, durability, subgroup, safety, and metabolic analyses. J Acquir Immune Defic Syndr. 2010 Sep;55(1):39-48. doi: 10.1097/QAI.0b013e3181da1287. Erratum in: J Acquir Immune Defic Syndr. 2011 Dec 1;58(4):e120. Dosage error in article text.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00369941 History of Changes
Other Study ID Numbers:	**0518-021** MK-**0518-021** 2006_519
Study First Received:	August 29, 2006
Results First Received:	September 18, 2009
Last Updated:	September 1, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Efavirenz	Antiviral Agents
Emtricitabine	Enzyme Inhibitors
Tenofovir	Molecular Mechanisms of Pharmacological Action
Tenofovir disoproxil	Nucleic Acid Synthesis Inhibitors
Anti-HIV Agents	Pharmacologic Actions

Anti-Infective Agents
Anti-Retroviral Agents
Reverse Transcriptase Inhibitors
Therapeutic Uses

ClinicalTrials.gov processed this record on March 10, 2016

TO TOP

For Patients and Families | **For Researchers** | **For Study Record Managers**

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A Study to Evaluate the Safety and Antiretroviral Activity of MK-0518 Versus Efavirenz in Treatment Naive HIV-Infected Patients, Each in Combination With TRUVADA (0518-021 EXT)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00369941

First received: August 29, 2006
Last updated: September 1, 2015
Last verified: September 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: September 18, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	HIV Infections
Interventions:	Drug: MK-0518 Drug: Comparator: efavirenz Drug: Comparator: Truvada Drug: Comparator: Placebo to MK-0518 Drug: Comparator: Placebo to efavirenz

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

Primary therapy period: 14-Sep-2006 to 06-May-2009

Multicenter (67) in the United States (18) and Ex-US (49)

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

No text entered.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Participant Flow: Overall Study

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
STARTED	**282**	**284**
Treated	**281**	**282**
COMPLETED	**210**	**184**
NOT COMPLETED	**72**	**100**
Never Treated	**1**	**2**
Adverse Event	**14**	**28**
Lack of Efficacy	**6**	**10**
Lost to Follow-up	**12**	**22**
Protocol Violation	**5**	**3**
Withdrawal by Subject	**5**	**18**
Pregnancy	**4**	**2**
Completed, Did Not Enter Extension	**5**	**6**
Moved	**11**	**5**
Treatment with Prohibited Medication	**3**	**1**
Employment Interfered with Study Visits	**1**	**0**
Study Site Terminated	**2**	**0**
Miscellaneous	**3**	**3**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

No text entered.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Total	Total of all reporting groups

Baseline Measures

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.	Total
Number of Participants [units: participants]	**281**	**282**	**563**
Age [units: years] Mean (Full Range)	**38 (19 to 67)**	**37 (19 to 71)**	**37 (19 to 71)**
Gender [units: participants]			
Female	**54**	**51**	**105**
Male	**227**	**231**	**458**
Race/Ethnicity, Customized [units: participants]			
White	**116**	**123**	**239**
Black	**33**	**23**	**56**
Asian	**36**	**32**	**68**
Hispanic	**60**	**67**	**127**
Others	**36**	**37**	**73**
Cluster of Differentiation 4 (CD4) Cell Count [units: Cells/mm^3] Mean (Full Range)	**219 (1 to 620)**	**217 (4 to 807)**	**218 (1 to 807)**
Plasma Human Immunodeficiency Virus (HIV) Ribonucleic Acid (RNA) [units: Copies/mL] Geometric Mean (Full Range)	**103205 (400 to 750000)**	**106215 (4410 to 750000)**	**104702 (400 to 750000)**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants Who Achieved Human Immunodeficiency Virus (HIV) Ribonucleic Acid (RNA) <50 Copies/mL at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary

Measure Title	Number of Participants Who Achieved Human Immunodeficiency Virus (HIV) Ribonucleic Acid (RNA) <50 Copies/mL at Week 48
Measure Description	Antiretroviral activity was evaluated for participants who achieved HIV RNA level <50 copies/mL at Week 48.
Time Frame	48 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had HIV RNA tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**280**	**281**
Number of Participants Who Achieved Human Immunodeficiency Virus (HIV) Ribonucleic Acid (RNA) <50 Copies/mL at Week 48 [units: Participants]	**241**	**230**

No statistical analysis provided for Number of Participants Who Achieved Human Immunodeficiency Virus (HIV) Ribonucleic Acid (RNA) <50 Copies/mL at Week 48

2. Primary: Number of Participants With Clinical Adverse Experiences (CAEs) at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants With Clinical Adverse Experiences (CAEs) at Week 48
Measure Description	An adverse experience (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Clinical Adverse Experiences (CAEs) at Week 48 [units: Participants]		
With CAEs	**253**	**272**
Without CAEs	**28**	**10**

No statistical analysis provided for Number of Participants With Clinical Adverse Experiences (CAEs) at Week 48

3. Primary: Number of Participants With Serious CAEs at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants With Serious CAEs at Week 48
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description

MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious CAEs at Week 48 [units: Participants]		
With Serious CAEs	**28**	**27**
Without Serious CAEs	**253**	**255**

No statistical analysis provided for Number of Participants With Serious CAEs at Week 48

4. Primary: Number of Participants With Drug-related CAEs at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants With Drug-related CAEs at Week 48
Measure Description	Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of

	TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Drug-related CAEs at Week 48 [units: Participants]		
With Drug-related CAEs	**124**	**217**
Without Drug-related CAEs	**157**	**65**

No statistical analysis provided for Number of Participants With Drug-related CAEs at Week 48

5. Primary: Number of Participants With Serious Drug-related CAEs at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants With Serious Drug-related CAEs at Week 48
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.

Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious Drug-related CAEs at Week 48 [units: Participants]		
With Serious Drug-related CAEs	**4**	**5**
Without Serious Drug-related CAEs	**277**	**277**

No statistical analysis provided for Number of Participants With Serious Drug-related CAEs at Week 48

6. Primary: Number of Participants That Died by Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants That Died by Week 48
Measure Description	All participant deaths in the span of 48 weeks on study were recorded.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Died by Week 48 [units: Participants]		
Died	**2**	**0**

Did Not Die	**279**	**282**

No statistical analysis provided for Number of Participants That Died by Week 48

7. Primary: Number of Participants That Discontinued With CAEs at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants That Discontinued With CAEs at Week 48
Measure Description	An adverse experience (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With CAEs at Week 48 [units: Participants]		
Discontinued with CAEs	**9**	**17**
Did Not Discontinue with CAEs	**272**	**265**

No statistical analysis provided for Number of Participants That Discontinued With CAEs at Week 48

8. Primary: Number of Participants That Discontinued With Serious CAEs at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants That Discontinued With Serious CAEs at Week 48
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With Serious CAEs at Week 48 [units: Participants]		
Discontinued with Serious CAEs	**7**	**4**
Did Not Discontinue with Serious CAEs	**274**	**278**

No statistical analysis provided for Number of Participants That Discontinued With Serious CAEs at Week 48

9. Primary: Number of Participants That Discontinued With Drug-related CAEs at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants That Discontinued With Drug-related CAEs at Week 48
Measure Description	Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	48 Weeks

Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With Drug-related CAEs at Week 48 [units: Participants]		
Discontinued with Drug-related CAEs	**3**	**11**
Did not Discontinue with Drug-related CAEs	**278**	**271**

No statistical analysis provided for Number of Participants That Discontinued With Drug-related CAEs at Week 48

10. Primary: Number of Participants That Discontinued With Serious Drug-related CAEs at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants That Discontinued With Serious Drug-related CAEs at Week 48
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With Serious Drug-related CAEs at Week 48 [units: Participants]		
Discontiued with Serious Drug-related CAEs	**1**	**2**
Did Not Discontinue with Serious Drug-related CAEs	**280**	**280**

No statistical analysis provided for Number of Participants That Discontinued With Serious Drug-related CAEs at Week 48

11. Primary: Number of Participants With Laboratory Adverse Experiences (LAEs) at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants With Laboratory Adverse Experiences (LAEs) at Week 48
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will

	take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Laboratory Adverse Experiences (LAEs) at Week 48 [units: Participants]		
With LAEs	**27**	**41**
Without LAEs	**254**	**241**

No statistical analysis provided for Number of Participants With Laboratory Adverse Experiences (LAEs) at Week 48

12. Primary: Number of Participants With Serious LAEs at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants With Serious LAEs at Week 48
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take

	one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious LAEs at Week 48 [units: Participants]		
With Serious LAEs	**0**	**1**
Without Serious LAEs	**281**	**281**

No statistical analysis provided for Number of Participants With Serious LAEs at Week 48

13. Primary: Number of Participants With Drug-related LAEs at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants With Drug-related LAEs at Week 48
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.

Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Drug-related LAEs at Week 48 [units: Participants]		
With Drug-related LAEs	**14**	**24**
Without Drug-related LAEs	**267**	**258**

No statistical analysis provided for Number of Participants With Drug-related LAEs at Week 48

14. Primary: Number of Participants With Serious Drug-related LAEs at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants With Serious Drug-related LAEs at Week 48
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed	**281**	**282**

[units: participants]		
Number of Participants With Serious Drug-related LAEs at Week 48 **[units: Participants]**		
With Serious Drug-related LAEs	**0**	**0**
Without Serious Drug-related LAEs	**281**	**282**

No statistical analysis provided for Number of Participants With Serious Drug-related LAEs at Week 48

15. Primary: Number of Participants Discontinued With LAEs at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants Discontinued With LAEs at Week 48
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed **[units: participants]**	**281**	**282**
Number of Participants Discontinued With LAEs at Week 48 **[units: Participants]**		
Discontinued with LAEs	**0**	**1**
Did Not Discontinue with LAEs	**281**	**281**

No statistical analysis provided for Number of Participants Discontinued With LAEs at Week 48

16. Primary: Number of Participants Discontinued With Drug-related LAEs at Week 48 [Time Frame: 48 Weeks]

Measure Type	Primary
Measure Title	Number of Participants Discontinued With Drug-related LAEs at Week 48
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse events (AEs) in this study were defined as "drug-related" if the investigator considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone.
Time Frame	48 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants Discontinued With Drug-related LAEs at Week 48 [units: Participants]		
Discontinued with Drug-related LAEs	**0**	**1**
Did Not Discontinue with Drug-related LAEs	**281**	**281**

No statistical analysis provided for Number of Participants Discontinued With Drug-related LAEs at Week 48

17. Secondary: Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 48 [Time Frame: 48 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 48
Measure Description	Antiretroviral activity was evaluated for participants who achieved HIV RNA level <400 copies/mL at Week 48.
Time Frame	48 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had HIV RNA tests performed were included in this analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**280**	**281**
Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 48 [units: Participants]	**252**	**241**

No statistical analysis provided for Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 48

18. Secondary: Change From Baseline in Cluster of Differentiation Antigen 4 (CD4) Cell Count at Week 48 [Time Frame: Baseline and Week 48]

Measure Type	Secondary
Measure Title	Change From Baseline in Cluster of Differentiation Antigen 4 (CD4) Cell Count at Week 48
Measure Description	Mean change from baseline at Week 48 in CD4 cell count (cells/mm3)
Time Frame	Baseline and Week 48
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
Observed failure approach assuming baseline-carry-forward for all failures, exclude other missing values. Baseline CD4 cell count (cells/mm3) was carried forward for participants who discontinued assigned therapy due to lack of efficacy.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**258**	**251**
Change From Baseline in Cluster of Differentiation Antigen 4 (CD4) Cell Count at Week 48 [units: CD4 Cell Count (cells/mm3)] Mean (95% Confidence Interval)	**189.1 (173.9 to 204.3)**	**163.3 (148.2 to 178.4)**

No statistical analysis provided for Change From Baseline in Cluster of Differentiation Antigen 4 (CD4) Cell Count at Week 48

19. Secondary: Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 96
Measure Description	Antiretroviral activity was evaluated for participants who achieved HIV RNA level <50 copies/mL at Week 96.
Time Frame	96 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had HIV RNA tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with

	creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 96 [units: Participants]	**228**	**222**

No statistical analysis provided for Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 96

20. Secondary: Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 96
Measure Description	Antiretroviral activity was evaluated for participants who achieved HIV RNA level <400 copies/mL at Week 96.
Time Frame	96 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had HIV RNA tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**

Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 96 **[units: Participants]**	**240**	**229**

No statistical analysis provided for Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 96

21. Secondary: Change From Baseline in CD4 Cell Count at Week 96 [Time Frame: Baseline and Week 96]

Measure Type	Secondary
Measure Title	Change From Baseline in CD4 Cell Count at Week 96
Measure Description	Mean change from baseline at Week 96 in CD4 cell count (cells/mm3)
Time Frame	Baseline and Week 96
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Observed failure approach assuming baseline-carry-forward for all failures, exclude other missing values. Baseline CD4 cell count (cells/mm3) was carried forward for participants who discontinued assigned therapy due to lack of efficacy.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed **[units: participants]**	**249**	**243**
Change From Baseline in CD4 Cell Count at Week 96 **[units: CD4 Cell Count (cells/mm3)]** **Mean (95% Confidence Interval)**	**239.6 (219.8 to 259.4)**	**224.8 (205.8 to 243.9)**

No statistical analysis provided for Change From Baseline in CD4 Cell Count at Week 96

22. Secondary: Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 156
Measure Description	Antiretroviral activity was evaluated for participants who achieved HIV RNA level <50 copies/mL at Week 156.
Time Frame	156 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had HIV RNA tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 156 [units: Participants]	**212**	**192**

No statistical analysis provided for Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 156

23. Secondary: Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 156
Measure Description	Antiretroviral activity was evaluated for participants who achieved HIV RNA level <400 copies/mL at Week 156.
Time Frame	156 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had HIV RNA tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 156 [units: Participants]	**224**	**203**

No statistical analysis provided for Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 156

24. Secondary: Change From Baseline in CD4 Cell Count at Week 156 [Time Frame: Baseline and Week 156]

Measure Type	Secondary
Measure Title	Change From Baseline in CD4 Cell Count at Week 156
Measure Description	Mean change from baseline at Week 156 in CD4 cell count (cells/mm3)
Time Frame	Baseline and Week 156
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Observed failure approach assuming baseline-carry-forward for all failures, exclude other missing values. Baseline CD4 cell count (cells/mm3) was carried forward for participants who discontinued assigned therapy due to lack of efficacy.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**236**	**226**
Change From Baseline in CD4 Cell Count at Week 156 [units: CD4 Cell Count (cells/mm3)] Mean (95% Confidence Interval)	**331.7 (309.3 to 354.2)**	**295.2 (271.3 to 319.0)**

No statistical analysis provided for Change From Baseline in CD4 Cell Count at Week 156

25. Secondary: Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 240
Measure Description	Antiretroviral activity was evaluated for participants who achieved HIV RNA level <50 copies/mL at Week 240.
Time Frame	240 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had HIV RNA tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**279**	**279**

Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 240 **[units: Participants]**	**198**	**171**

No statistical analysis provided for Number of Participants Who Achieved HIV RNA <50 Copies/mL at Week 240

26. Secondary: Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 240
Measure Description	Antiretroviral activity was evaluated for participants who achieved HIV RNA level <400 copies/mL at Week 240.
Time Frame	240 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had HIV RNA tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed **[units: participants]**	**279**	**279**
Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 240 **[units: Participants]**	**206**	**181**

No statistical analysis provided for Number of Participants Who Achieved HIV RNA <400 Copies/mL at Week 240

27. Secondary: Change From Baseline in CD4 Cell Count at Week 240 [Time Frame: Baseline and Week 240]

Measure Type	Secondary

Measure Title	Change From Baseline in CD4 Cell Count at Week 240
Measure Description	Mean change from baseline at Week 240 in CD4 cell count (cells/mm3)
Time Frame	Baseline and Week 240
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Observed failure approach assuming baseline-carry-forward for all failures, exclude other missing values. Baseline CD4 cell count (cells/mm3) was carried forward for participants who discontinued assigned therapy due to lack of efficacy.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**222**	**212**
Change From Baseline in CD4 Cell Count at Week 240 [units: CD4 Cell Count (cells/mm3)] Mean (95% Confidence Interval)	**373.7 (344.6 to 402.8)**	**311.6 (283.9 to 339.4)**

No statistical analysis provided for Change From Baseline in CD4 Cell Count at Week 240

28. Secondary: Number of Participants With Nervous System Symptoms Assessed by Review of Accumulated Safety Data up to Week 8 [Time Frame: 8 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Nervous System Symptoms Assessed by Review of Accumulated Safety Data up to Week 8
Measure Description	Participants with dizziness, insomnia, somnolence, concentration impaired, depression, nightmare, confusional state, suicidal ideation, nervous system disorder, psychotic disorder, abnormal dreams, suicide attempt, acute psychosis, delirium, depressed level of consciousness, hallucination, auditory hallucination, completed suicide, and major depression
Time Frame	8 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Nervous System Symptoms Assessed by Review of Accumulated Safety Data up to Week 8 [units: Participants]		
With Nervous System Symptoms	**57**	**147**
Without Nervous System Symptoms	**224**	**135**

No statistical analysis provided for Number of Participants With Nervous System Symptoms Assessed by Review of Accumulated Safety Data up to Week 8

29. Secondary: Number of Participants With CAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With CAEs at Week 96
Measure Description	An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With CAEs at Week 96 [units: Participants]		
With CAEs	**265**	**274**
Without CAEs	**16**	**8**

No statistical analysis provided for Number of Participants With CAEs at Week 96

30. Secondary: Number of Participants With CAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With CAEs at Week 156
Measure Description	An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With CAEs at Week 156 [units: Participants]		
With CAEs	**267**	**276**
Without CAEs	**14**	**6**

No statistical analysis provided for Number of Participants With CAEs at Week 156

31. Secondary: Number of Participants With CAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With CAEs at Week 240
Measure Description	An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.

Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With CAEs at Week 240 [units: Participants]		
With CAEs	**271**	**276**
Without CAEs	**10**	**6**

No statistical analysis provided for Number of Participants With CAEs at Week 240

32. Secondary: Number of Participants With Serious CAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Serious CAEs at Week 96
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious CAEs at Week 96 [units: Participants]		
With Serious CAEs	**37**	**33**

Without Serious CAEs	**244**	**249**

No statistical analysis provided for Number of Participants With Serious CAEs at Week 96

33. Secondary: Number of Participants With Serious CAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Serious CAEs at Week 156
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious CAEs at Week 156 [units: Participants]		
With Serious CAEs	**46**	**46**
Without Serious CAEs	**235**	**236**

No statistical analysis provided for Number of Participants With Serious CAEs at Week 156

34. Secondary: Number of Participants With Serious CAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Serious CAEs at Week 240
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious CAEs at Week 240 [units: Participants]		
With Serious CAEs	**57**	**57**
Without Serious CAEs	**224**	**225**

No statistical analysis provided for Number of Participants With Serious CAEs at Week 240

35. Secondary: Number of Participants With Drug-related CAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Drug-related CAEs at Week 96
Measure Description	Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	96 Weeks

Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Drug-related CAEs at Week 96 [units: Participants]		
With drug-related CAEs	**132**	**220**
Without drug-related CAEs	**149**	**62**

No statistical analysis provided for Number of Participants With Drug-related CAEs at Week 96

36. Secondary: Number of Participants With Drug-related CAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Drug-related CAEs at Week 156
Measure Description	Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Drug-related CAEs at Week 156 [units: Participants]		
With drug-related CAEs	**139**	**225**
Without drug-related CAEs	**142**	**57**

No statistical analysis provided for Number of Participants With Drug-related CAEs at Week 156

37. Secondary: Number of Participants With Drug-related CAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Drug-related CAEs at Week 240
Measure Description	Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Drug-related CAEs at Week 240 [units: Participants]		
With drug-related CAEs	**146**	**226**
Without drug-related CAEs	**135**	**56**

No statistical analysis provided for Number of Participants With Drug-related CAEs at Week 240

38. Secondary: Number of Participants With Serious Drug-related CAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Serious Drug-related CAEs at Week 96
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious Drug-related CAEs at Week 96 [units: Participants]		
With Serious Drug-related CAEs	**6**	**5**
Without Serious Drug-related CAEs	**275**	**277**

No statistical analysis provided for Number of Participants With Serious Drug-related CAEs at Week 96

39. Secondary: Number of Participants With Serious Drug-related CAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Serious Drug-related CAEs at Week 156
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed		

[units: participants]	281	282
Number of Participants With Serious Drug-related CAEs at Week 156 **[units: Participants]**		
With Serious Drug-related CAEs	6	6
Without Serious Drug-related CAEs	275	276

No statistical analysis provided for Number of Participants With Serious Drug-related CAEs at Week 156

40. Secondary: Number of Participants With Serious Drug-related CAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Serious Drug-related CAEs at Week 240
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed **[units: participants]**	**281**	**282**
Number of Participants With Serious Drug-related CAEs at Week 240 **[units: Participants]**		

With Serious Drug-related CAEs	**8**	**7**
Without Serious Drug-related CAEs	**273**	**275**

No statistical analysis provided for Number of Participants With Serious Drug-related CAEs at Week 240

41. Secondary: Number of Participants That Died by Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Died by Week 96
Measure Description	All participant deaths in the span of 96 weeks on study were recorded.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Died by Week 96 [units: Participants]		
Died	**3**	**0**
Did Not Die	**278**	**282**

No statistical analysis provided for Number of Participants That Died by Week 96

42. Secondary: Number of Participants That Died by Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Died by Week 156
Measure Description	All participant deaths in the span of 156 weeks on study were recorded.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Died by Week 156 [units: Participants]		
Died	**4**	**1**
Did Not Die	**277**	**281**

No statistical analysis provided for Number of Participants That Died by Week 156

43. Secondary: Number of Participants That Died by Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Died by Week 240
Measure Description	All participant deaths in the span of 240 weeks on study were recorded.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Died by Week 240 [units: Participants]		
Died	**5**	**5**
Did Not Die	**276**	**277**

No statistical analysis provided for Number of Participants That Died by Week 240

44. Secondary: Number of Participants That Discontinued With CAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Discontinued With CAEs at Week 96
Measure Description	An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With CAEs at Week 96 [units: Participants]		
Discontinued With CAEs	**10**	**17**
Did Not Discontinue With CAEs	**271**	**265**

No statistical analysis provided for Number of Participants That Discontinued With CAEs at Week 96

45. Secondary: Number of Participants That Discontinued With CAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Discontinued With CAEs at Week 156
Measure Description	An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime,

	and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With CAEs at Week 156 [units: Participants]		
Discontinued With CAEs	**13**	**21**
Did Not Discontinue With CAEs	**268**	**261**

No statistical analysis provided for Number of Participants That Discontinued With CAEs at Week 156

46. Secondary: Number of Participants That Discontinued With CAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Discontinued With CAEs at Week 240
Measure Description	An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the product.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.

Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With CAEs at Week 240 [units: Participants]		
Discontinued With CAEs	**14**	**25**
Did Not Discontinue With CAEs	**267**	**257**

No statistical analysis provided for Number of Participants That Discontinued With CAEs at Week 240

47. Secondary: Number of Participants That Discontinued With Drug-related CAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Discontinued With Drug-related CAEs at Week 96
Measure Description	Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With Drug-related CAEs at Week 96 [units: Participants]		
Discontinued With Drug-Related CAEs	**3**	**12**
Did Not Discontinue With Drug-Related CAEs	**278**	**270**

No statistical analysis provided for Number of Participants That Discontinued With Drug-related CAEs at Week 96

48. Secondary: Number of Participants That Discontinued With Drug-related CAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Discontinued With Drug-related CAEs at Week 156
Measure Description	Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With Drug-related CAEs at Week 156 [units: Participants]		
Discontinued With Drug-related CAEs	**3**	**14**
Did Not Discontinue With Drug-related CAEs	**278**	**268**

No statistical analysis provided for Number of Participants That Discontinued With Drug-related CAEs at Week 156

49. Secondary: Number of Participants That Discontinued With Drug-related CAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary

Measure Title	Number of Participants That Discontinued With Drug-related CAEs at Week 240
Measure Description	Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With Drug-related CAEs at Week 240 [units: Participants]		
Discontinued With Drug-related CAEs	**3**	**14**
Did Not Discontinue With Drug-related CAEs	**278**	**268**

No statistical analysis provided for Number of Participants That Discontinued With Drug-related CAEs at Week 240

50. Secondary: Number of Participants That Discontinued With Serious CAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Discontinued With Serious CAEs at Week 96
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With Serious CAEs at Week 96 [units: Participants]		
Discontinued With Serious CAEs	**8**	**5**
Did Not Discontinue With Serious CAEs	**273**	**277**

No statistical analysis provided for Number of Participants That Discontinued With Serious CAEs at Week 96

51. Secondary: Number of Participants That Discontinued With Serious CAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Discontinued With Serious CAEs at Week 156
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With Serious CAEs at Week 156 [units: Participants]		
Discontinued With Serious CAEs	**10**	**6**
Did Not Discontinue With Serious CAEs	**271**	**276**

No statistical analysis provided for Number of Participants That Discontinued With Serious CAEs at Week 156

52. Secondary: Number of Participants That Discontinued With Serious CAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Discontinued With Serious CAEs at Week 240
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime,

	and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With Serious CAEs at Week 240 [units: Participants]		
Discontinued With Serious CAEs	**11**	**10**
Did Not Discontinue With Serious CAEs	**270**	**272**

No statistical analysis provided for Number of Participants That Discontinued With Serious CAEs at Week 240

53. Secondary: Number of Participants That Discontinued With Serious Drug-related CAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Discontinued With Serious Drug-related CAEs at Week 96
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants That Discontinued With Serious Drug-related CAEs at Week 96 [units: Participants]		
Discontinued With Serious Drug-related CAEs	**1**	**2**
Did Not Discontinue With Serious Drug-related CAEs	**280**	**280**

No statistical analysis provided for Number of Participants That Discontinued With Serious Drug-related CAEs at Week 96

54. Secondary: Number of Participants That Discontinued With Serious Drug-related CAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Discontinued With Serious Drug-related CAEs at Week 156
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**

Number of Participants That Discontinued With Serious Drug-related CAEs at Week 156 **[units: Participants]**		
Discontinued With Serious Drug-related CAEs	**1**	**2**
Did Not Discontinue With Serious Drug-related CAEs	**280**	**280**

No statistical analysis provided for Number of Participants That Discontinued With Serious Drug-related CAEs at Week 156

55. Secondary: Number of Participants That Discontinued With Serious Drug-related CAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Discontinued With Serious Drug-related CAEs at Week 240
Measure Description	Serious CAEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed **[units: participants]**	**281**	**282**
Number of Participants That Discontinued With Serious Drug-related CAEs at Week 240 **[units: Participants]**		
Discontinued With Serious Drug-related CAEs	**1**	**2**

Did Not Discontinue With Serious Drug-related CAEs	**280**	**280**

No statistical analysis provided for Number of Participants That Discontinued With Serious Drug-related CAEs at Week 240

56. Secondary: Number of Participants With LAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With LAEs at Week 96
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With LAEs at Week 96 [units: Participants]		
With LAEs	**33**	**53**
Without LAEs	**248**	**229**

No statistical analysis provided for Number of Participants With LAEs at Week 96

57. Secondary: Number of Participants With LAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With LAEs at Week 156
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With LAEs at Week 156 [units: Participants]		
With LAEs	**41**	**63**
Without LAEs	**240**	**219**

No statistical analysis provided for Number of Participants With LAEs at Week 156

58. Secondary: Number of Participants With LAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With LAEs at Week 240
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With LAEs at Week 240 [units: Participants]		
With LAEs	**56**	**77**
Without LAEs	**225**	**205**

No statistical analysis provided for Number of Participants With LAEs at Week 240

59. Secondary: Number of Participants With Drug-related LAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Drug-related LAEs at Week 96
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Drug-related LAEs at Week 96 [units: Participants]		
With Drug-related LAEs	**18**	**29**
Without Drug-related LAEs	**263**	**253**

No statistical analysis provided for Number of Participants With Drug-related LAEs at Week 96

60. Secondary: Number of Participants With Drug-related LAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Drug-related LAEs at Week 156
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will

	take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Drug-related LAEs at Week 156 [units: Participants]		
With Drug-related LAEs	**22**	**33**
Without Drug-related LAEs	**259**	**249**

No statistical analysis provided for Number of Participants With Drug-related LAEs at Week 156

61. Secondary: Number of Participants With Drug-related LAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Drug-related LAEs at Week 240
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take

	one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Drug-related LAEs at Week 240 [units: Participants]		
With Drug-related LAEs	**26**	**43**
Without Drug-related LAEs	**255**	**239**

No statistical analysis provided for Number of Participants With Drug-related LAEs at Week 240

62. Secondary: Number of Participants With Serious LAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Serious LAEs at Week 96
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.

Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious LAEs at Week 96 [units: Participants]		
With Serious LAEs	**0**	**1**
Without Serious LAEs	**281**	**281**

No statistical analysis provided for Number of Participants With Serious LAEs at Week 96

63. Secondary: Number of Participants With Serious LAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Serious LAEs at Week 156
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious LAEs at Week 156		

[units: Participants]		
With Serious LAEs	0	2
Without Serious LAEs	281	280

No statistical analysis provided for Number of Participants With Serious LAEs at Week 156

64. Secondary: Number of Participants With Serious LAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Serious LAEs at Week 240
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious LAEs at Week 240 [units: Participants]		
With Serious LAEs	**0**	**2**
Without Serious LAEs	**281**	**280**

No statistical analysis provided for Number of Participants With Serious LAEs at Week 240

65. Secondary: Number of Participants With Serious Drug-related LAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Serious Drug-related LAEs at Week 96
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious Drug-related LAEs at Week 96 [units: Participants]		
With Serious Drug-related CAEs	**0**	**0**
Without Serious Drug-related CAEs	**281**	**282**

No statistical analysis provided for Number of Participants With Serious Drug-related LAEs at Week 96

66. Secondary: Number of Participants With Serious Drug-related LAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Serious Drug-related LAEs at Week 156
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious Drug-related LAEs at Week 156 [units: Participants]		
With Serious Drug-related CAEs	**0**	**1**
Without Serious Drug-related CAEs	**281**	**281**

No statistical analysis provided for Number of Participants With Serious Drug-related LAEs at Week 156

67. Secondary: Number of Participants With Serious Drug-related LAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Serious Drug-related LAEs at Week 240
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Serious AEs are any AEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants With Serious Drug-related LAEs at Week 240 [units: Participants]		
With Serious Drug-related LAEs	**0**	**1**
Without Serious Drug-related LAEs	**281**	**281**

No statistical analysis provided for Number of Participants With Serious Drug-related LAEs at Week 240

68. Secondary: Number of Participants Discontinued With LAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	

	Number of Participants Discontinued With LAEs at Week 96
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	**Efavirenz 600 mg q.h.s.**
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants Discontinued With LAEs at Week 96 [units: Participants]		
Discontinued With LAEs	**0**	**2**
Did Not Discontinue With LAEs	**281**	**280**

No statistical analysis provided for Number of Participants Discontinued With LAEs at Week 96

69. Secondary: Number of Participants Discontinued With LAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Discontinued With LAEs at Week 156
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants Discontinued With LAEs at Week 156 [units: Participants]		
Discontinued With LAEs	**0**	**3**
Did Not Discontinue With LAEs	**281**	**279**

No statistical analysis provided for Number of Participants Discontinued With LAEs at Week 156

70. Secondary: Number of Participants Discontinued With LAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Discontinued With LAEs at Week 240
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to

	efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants Discontinued With LAEs at Week 240 [units: Participants]		
Discontinued With LAEs	**0**	**3**
Did Not Discontinue With LAEs	**281**	**279**

No statistical analysis provided for Number of Participants Discontinued With LAEs at Week 240

71. Secondary: Number of Participants Discontinued With Drug-related LAEs at Week 96 [Time Frame: 96 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Discontinued With Drug-related LAEs at Week 96
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	96 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime,

	and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants Discontinued With Drug-related LAEs at Week 96 [units: Participants]		
Discontinued With Drug-related LAEs	**0**	**1**
Did Not Discontinue With Drug-related LAEs	**281**	**281**

No statistical analysis provided for Number of Participants Discontinued With Drug-related LAEs at Week 96

72. Secondary: Number of Participants Discontinued With Drug-related LAEs at Week 156 [Time Frame: 156 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Discontinued With Drug-related LAEs at Week 156
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	156 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants Discontinued With Drug-related LAEs at Week 156 [units: Participants]		
Discontinued With Drug-related LAEs	**0**	**2**
Did Not Discontinue With Drug-related LAEs	**281**	**280**

No statistical analysis provided for Number of Participants Discontinued With Drug-related LAEs at Week 156

73. Secondary: Number of Participants Discontinued With Drug-related LAEs at Week 240 [Time Frame: 240 Weeks]

Measure Type	Secondary
Measure Title	Number of Participants Discontinued With Drug-related LAEs at Week 240
Measure Description	A laboratory AE is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the study product, whether or not considered related to the use of the product. Adverse experiences (AEs) in this study were defined as "drug-related" if the investigator, who is a qualified physician, considered the AE as possibly, probably, or definitely related to MK-0518 or efavirenz alone or in combination with TRUVADA® or to TRUVADA® alone according to his/her best clinical judgment.
Time Frame	240 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who took study medication and had any laboratory tests performed were included in the analysis.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg, which can be taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, which will be taken PO at bedtime (q.h.s.) on an empty stomach preferably at bedtime. All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) with food, daily with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg, which will be taken by mouth (PO) at bedtime (q.h.s.) on an empty stomach preferably at bedtime, and placebo to MK-0518, which will be taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Measured Values

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Number of Participants Analyzed [units: participants]	**281**	**282**
Number of Participants Discontinued With Drug-related LAEs at Week 240		

[units: Participants]		
Discontinued With Drug-related LAEs	0	2
Did Not Discontinue With Drug-related LAEs	281	280

No statistical analysis provided for Number of Participants Discontinued With Drug-related LAEs at Week 240

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	240 weeks
Additional Description	Adverse events are reported for the entire 240-week study.

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, taken PO (q.h.s.) on an empty stomach preferably at bedtime (q.h.s.). All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) daily with food with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg taken by mouth on an empty stomach preferably at bedtime (q.h.s.), and placebo to MK-0518 taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Serious Adverse Events

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Total, serious adverse events		
# participants affected / at risk	57/281 (20.28%)	59/282 (20.92%)
Blood and lymphatic system disorders		
Anaemia † [1]		
# participants affected / at risk	3/281 (1.07%)	1/282 (0.35%)
# events	3	1
Eosinophilia † [1]		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Iron deficiency anaemia † [1]		
# participants affected / at risk	1/281 (0.36%)	1/282 (0.35%)
# events	1	1
Lymphadenitis † [1]		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Pancytopenia † [1]		

# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Cardiac disorders		
Acute myocardial infarction † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Cardiac failure † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Coronary artery disease † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Congenital, familial and genetic disorders		
Branchial cleft cyst † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Heart disease congenital † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Eye disorders		
Conjunctivitis † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Uveitis † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	1/281 (0.36%)	1/282 (0.35%)
# events	1	1
Anal fistula † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Colitis † 1		
# participants affected / at risk	1/281 (0.36%)	1/282 (0.35%)
# events	1	1
Duodenal ulcer † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Gastrointestinal disorder † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Nausea † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1

Oesophagitis † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Pancreatitis † 1		
# participants affected / at risk	2/281 (0.71%)	1/282 (0.35%)
# events	2	1
Pancreatitis acute † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Peptic ulcer † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Proctalgia † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Rectal haemorrhage † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Vomiting † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
General disorders		
Chest pain † 1		
# participants affected / at risk	1/281 (0.36%)	2/282 (0.71%)
# events	1	2
Death † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Hepatobiliary disorders		
Cholangitis † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Cholecystitis chronic † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Immune system disorders		
Immune reconstitution syndrome † 1		
# participants affected / at risk	5/281 (1.78%)	2/282 (0.71%)
# events	5	2
Infections and infestations		
Abscess limb † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Appendicitis † 1		

# participants affected / at risk	0/281 (0.00%)	3/282 (1.06%)
# events	0	3
Bacteraemia † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Bone tuberculosis † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Cellulitis † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Cytomegalovirus colitis † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Dengue fever † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Diarrhoea infectious † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Endometritis † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Enterocolitis infectious † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Extrapulmonary tuberculosis † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Gastroenteritis † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Hepatitis B † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Hepatitis C † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Herpes zoster † 1		
# participants affected / at risk	1/281 (0.36%)	1/282 (0.35%)
# events	1	1
Infectious mononucleosis † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Influenza † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)

# events	0	2
Lung infection † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Lymphangitis † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Meningitis † 1		
# participants affected / at risk	2/281 (0.71%)	0/282 (0.00%)
# events	2	0
Mycobacterium avium complex infection † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Neurosyphilis † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Oesophageal candidiasis † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Orchitis † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Pneumocystis jiroveci pneumonia † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Pneumonia † 1		
# participants affected / at risk	2/281 (0.71%)	5/282 (1.77%)
# events	2	5
Pulmonary tuberculosis † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Pyelonephritis † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Pyelonephritis acute † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Secondary syphilis † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Sepsis † 1		
# participants affected / at risk	1/281 (0.36%)	1/282 (0.35%)
# events	1	1
Septic shock † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)

# events	0	2
Subcutaneous abscess † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Syphilis † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Urinary tract infection † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Vestibular neuronitis † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Viral upper respiratory tract infection † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Injury, poisoning and procedural complications		
Accidental exposure † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Accidental overdose † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Alcohol poisoning † 1		
# participants affected / at risk	1/281 (0.36%)	1/282 (0.35%)
# events	1	1
Cervical vertebral fracture † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Chemical poisoning † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Femoral neck fracture † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Intentional overdose † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Joint dislocation † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Laceration † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Limb injury † 1		

# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Maternal exposure during pregnancy † 1		
# participants affected / at risk	1/281 (0.36%)	1/282 (0.35%)
# events	1	1
Multiple injuries † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Rib fracture † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Subdural haematoma † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Toxicity to various agents † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Traumatic lung injury † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Investigations		
Alanine aminotransferase increased † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Aspartate aminotransferase increased † 1		
# participants affected / at risk	0/281 (0.00%)	2/282 (0.71%)
# events	0	2
Blood alkaline phosphatase increased † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	2	0
Intervertebral disc protrusion † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Musculoskeletal pain † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Myopathy † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		

Anal cancer † 1		
# participants affected / at risk	**0/281 (0.00%)**	**2/282 (0.71%)**
# events	**0**	**2**
Anogenital warts † 1		
# participants affected / at risk	**1/281 (0.36%)**	**0/282 (0.00%)**
# events	**1**	**0**
Basal cell carcinoma † 1		
# participants affected / at risk	**2/281 (0.71%)**	**3/282 (1.06%)**
# events	**3**	**3**
Bone neoplasm malignant † 1		
# participants affected / at risk	**0/281 (0.00%)**	**1/282 (0.35%)**
# events	**0**	**1**
Breast cancer † 1		
# participants affected / at risk	**2/281 (0.71%)**	**0/282 (0.00%)**
# events	**2**	**0**
Kaposi's sarcoma AIDS related † 1		
# participants affected / at risk	**2/281 (0.71%)**	**6/282 (2.13%)**
# events	**2**	**7**
Leukaemia † 1		
# participants affected / at risk	**0/281 (0.00%)**	**1/282 (0.35%)**
# events	**0**	**1**
Lung cancer metastatic † 1		
# participants affected / at risk	**1/281 (0.36%)**	**0/282 (0.00%)**
# events	**1**	**0**
Lung neoplasm malignant † 1		
# participants affected / at risk	**1/281 (0.36%)**	**0/282 (0.00%)**
# events	**1**	**0**
Plasmablastic lymphoma † 1		
# participants affected / at risk	**0/281 (0.00%)**	**1/282 (0.35%)**
# events	**0**	**1**
Uterine leiomyoma † 1		
# participants affected / at risk	**0/281 (0.00%)**	**1/282 (0.35%)**
# events	**0**	**1**
Nervous system disorders		
Cerebral haemorrhage † 1		
# participants affected / at risk	**1/281 (0.36%)**	**0/282 (0.00%)**
# events	**1**	**0**
Convulsion † 1		
# participants affected / at risk	**1/281 (0.36%)**	**1/282 (0.35%)**
# events	**1**	**1**
Dizziness † 1		
# participants affected / at risk	**0/281 (0.00%)**	**1/282 (0.35%)**
# events	**0**	**1**
Hypoaesthesia † 1		
# participants affected / at risk	**1/281 (0.36%)**	**0/282 (0.00%)**

# events	1	0
Migraine † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	6	0
Nervous system disorder † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Syncope † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Psychiatric disorders		
Anxiety † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Conversion disorder † 1		
# participants affected / at risk	0/281 (0.00%)	2/282 (0.71%)
# events	0	2
Depression † 1		
# participants affected / at risk	3/281 (1.07%)	3/282 (1.06%)
# events	6	3
Drug abuse † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Mental disorder † 1		
# participants affected / at risk	1/281 (0.36%)	1/282 (0.35%)
# events	1	1
Psychosomatic disease † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Psychotic disorder † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Schizoaffective disorder † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1
Suicidal ideation † 1		
# participants affected / at risk	1/281 (0.36%)	0/282 (0.00%)
# events	1	0
Suicide attempt † 1		
# participants affected / at risk	4/281 (1.42%)	0/282 (0.00%)
# events	4	0
Renal and urinary disorders		
Urinary bladder haemorrhage † 1		
# participants affected / at risk	0/281 (0.00%)	1/282 (0.35%)
# events	0	1

Reproductive system and breast disorders		
Menorrhagia † 1		
# participants affected / at risk	**0/281 (0.00%)**	**1/282 (0.35%)**
# events	**0**	**1**
Respiratory, thoracic and mediastinal disorders		
Bronchial hyperreactivity † 1		
# participants affected / at risk	**1/281 (0.36%)**	**0/282 (0.00%)**
# events	**1**	**0**
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**1/281 (0.36%)**	**0/282 (0.00%)**
# events	**1**	**0**
Haemoptysis † 1		
# participants affected / at risk	**0/281 (0.00%)**	**1/282 (0.35%)**
# events	**0**	**1**
Hypoxia † 1		
# participants affected / at risk	**1/281 (0.36%)**	**0/282 (0.00%)**
# events	**1**	**0**
Pleural effusion † 1		
# participants affected / at risk	**0/281 (0.00%)**	**1/282 (0.35%)**
# events	**0**	**1**
Respiratory failure † 1		
# participants affected / at risk	**1/281 (0.36%)**	**0/282 (0.00%)**
# events	**1**	**0**
Sleep apnoea syndrome † 1		
# participants affected / at risk	**1/281 (0.36%)**	**0/282 (0.00%)**
# events	**1**	**0**
Vascular disorders		
Arteriosclerosis obliterans † 1		
# participants affected / at risk	**0/281 (0.00%)**	**1/282 (0.35%)**
# events	**0**	**1**
Deep vein thrombosis † 1		
# participants affected / at risk	**1/281 (0.36%)**	**0/282 (0.00%)**
# events	**1**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	240 weeks
Additional Description	Adverse events are reported for the entire 240-week study.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
MK-0518 400 mg b.i.d.	MK-0518 400 mg taken by mouth (PO) twice a day (b.i.d.) without regard to food, and placebo to efavirenz, taken PO (q.h.s.) on an empty stomach preferably at bedtime (q.h.s.). All participants will take one tablet of TRUVADA® (200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) daily with food with the morning dose of MK-0518. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.
Efavirenz 600 mg q.h.s.	Efavirenz 600 mg taken by mouth on an empty stomach preferably at bedtime (q.h.s.), and placebo to MK-0518 taken PO twice a day (b.i.d.) without regard to food. All participants will take one tablet of TRUVADA® with food, daily with the morning dose of placebo. Dosing interval adjustment of TRUVADA® is recommended in all participants with creatinine clearance 30-49 mL/min.

Other Adverse Events

	MK-0518 400 mg b.i.d.	Efavirenz 600 mg q.h.s.
Total, other (not including serious) adverse events		
# participants affected / at risk	**257/281 (91.46%)**	**263/282 (93.26%)**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**24/281 (8.54%)**	**19/282 (6.74%)**
# events	**30**	**23**
Abdominal pain upper † 1		
# participants affected / at risk	**8/281 (2.85%)**	**19/282 (6.74%)**
# events	**16**	**20**
Diarrhoea † 1		
# participants affected / at risk	**72/281 (25.62%)**	**76/282 (26.95%)**
# events	**104**	**105**
Dyspepsia † 1		
# participants affected / at risk	**25/281 (8.90%)**	**14/282 (4.96%)**
# events	**27**	**18**
Flatulence † 1		
# participants affected / at risk	**14/281 (4.98%)**	**19/282 (6.74%)**
# events	**17**	**19**
Nausea † 1		
# participants affected / at risk	**47/281 (16.73%)**	**41/282 (14.54%)**
# events	**68**	**52**
Vomiting † 1		
# participants affected / at risk	**23/281 (8.19%)**	**30/282 (10.64%)**
# events	**29**	**38**
General disorders		
Asthenia † 1		
# participants affected / at risk	**17/281 (6.05%)**	**16/282 (5.67%)**
# events	**24**	**16**

Fatigue † 1		
# participants affected / at risk	**26/281 (9.25%)**	**38/282 (13.48%)**
# events	**29**	**46**
Pyrexia † 1		
# participants affected / at risk	**44/281 (15.66%)**	**39/282 (13.83%)**
# events	**62**	**50**
Infections and infestations		
Bronchitis † 1		
# participants affected / at risk	**29/281 (10.32%)**	**30/282 (10.64%)**
# events	**48**	**48**
Gastroenteritis † 1		
# participants affected / at risk	**17/281 (6.05%)**	**19/282 (6.74%)**
# events	**19**	**20**
Genital herpes † 1		
# participants affected / at risk	**12/281 (4.27%)**	**15/282 (5.32%)**
# events	**17**	**19**
Herpes zoster † 1		
# participants affected / at risk	**14/281 (4.98%)**	**16/282 (5.67%)**
# events	**17**	**19**
Influenza † 1		
# participants affected / at risk	**33/281 (11.74%)**	**38/282 (13.48%)**
# events	**58**	**68**
Nasopharyngitis † 1		
# participants affected / at risk	**75/281 (26.69%)**	**63/282 (22.34%)**
# events	**121**	**123**
Pharyngitis † 1		
# participants affected / at risk	**27/281 (9.61%)**	**26/282 (9.22%)**
# events	**33**	**33**
Sinusitis † 1		
# participants affected / at risk	**23/281 (8.19%)**	**23/282 (8.16%)**
# events	**31**	**31**
Upper respiratory tract infection † 1		
# participants affected / at risk	**60/281 (21.35%)**	**57/282 (20.21%)**
# events	**95**	**85**
Investigations		
Alanine aminotransferase increased † 1		
# participants affected / at risk	**19/281 (6.76%)**	**28/282 (9.93%)**
# events	**33**	**49**
Aspartate aminotransferase increased † 1		
# participants affected / at risk	**21/281 (7.47%)**	**25/282 (8.87%)**
# events	**37**	**44**
Metabolism and nutrition disorders		
Decreased appetite † 1		
# participants affected / at risk	**12/281 (4.27%)**	**19/282 (6.74%)**
# events	**18**	**20**

Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**24/281 (8.54%)**	**33/282 (11.70%)**
# events	**29**	**34**
Back pain † 1		
# participants affected / at risk	**34/281 (12.10%)**	**28/282 (9.93%)**
# events	**43**	**34**
Myalgia † 1		
# participants affected / at risk	**11/281 (3.91%)**	**15/282 (5.32%)**
# events	**12**	**19**
Pain in extremity † 1		
# participants affected / at risk	**18/281 (6.41%)**	**15/282 (5.32%)**
# events	**23**	**17**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**46/281 (16.37%)**	**108/282 (38.30%)**
# events	**49**	**140**
Headache † 1		
# participants affected / at risk	**73/281 (25.98%)**	**80/282 (28.37%)**
# events	**127**	**109**
Somnolence † 1		
# participants affected / at risk	**3/281 (1.07%)**	**22/282 (7.80%)**
# events	**5**	**27**
Psychiatric disorders		
Abnormal dreams † 1		
# participants affected / at risk	**23/281 (8.19%)**	**37/282 (13.12%)**
# events	**29**	**43**
Anxiety † 1		
# participants affected / at risk	**25/281 (8.90%)**	**31/282 (10.99%)**
# events	**25**	**31**
Depression † 1		
# participants affected / at risk	**27/281 (9.61%)**	**33/282 (11.70%)**
# events	**32**	**38**
Insomnia † 1		
# participants affected / at risk	**44/281 (15.66%)**	**42/282 (14.89%)**
# events	**56**	**49**
Nightmare † 1		
# participants affected / at risk	**10/281 (3.56%)**	**15/282 (5.32%)**
# events	**12**	**19**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**47/281 (16.73%)**	**34/282 (12.06%)**
# events	**64**	**47**
Oropharyngeal pain † 1		

# participants affected / at risk	22/281 (7.83%)	15/282 (5.32%)
# events	22	15
Rhinitis allergic † 1		
# participants affected / at risk	18/281 (6.41%)	6/282 (2.13%)
# events	20	8
Skin and subcutaneous tissue disorders		
Pruritus † 1		
# participants affected / at risk	12/281 (4.27%)	15/282 (5.32%)
# events	12	15
Rash † 1		
# participants affected / at risk	22/281 (7.83%)	39/282 (13.83%)
# events	26	46
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	18/281 (6.41%)	18/282 (6.38%)
# events	20	20

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 14.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

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More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: The Sponsor must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation. Any information identified by the Sponsor as confidential must be deleted prior to submission. Sponsor review can be expedited to meet publication guidelines.

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Publications of Results:

Lennox JL, DeJesus E, Lazzarin A, Pollard RB, Madruga JV, Berger DS, Zhao J, Xu X, Williams-Diaz A, Rodgers AJ, Barnard RJ, Miller MD, DiNubile MJ, Nguyen BY, Leavitt R, Sklar P; STARTMRK investigators. Safety and efficacy of raltegravir-based versus efavirenz-based combination therapy in treatment-naive patients with HIV-1 infection: a multicentre, double-blind randomised controlled trial. Lancet. 2009 Sep 5;374(9692):796-806. doi: 10.1016/S0140-6736(09)60918-1. Epub 2009 Aug 3. Erratum in: Lancet. 2009 Dec 19-2010 Jan 1;374(9707):2054. Lancet. 2009 Sep 5;374(9692):786.

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ClinicalTrials.gov Identifier:	NCT00369941 History of Changes
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Health Authority:	United States: Food and Drug Administration

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