Trial record **1 of 1** for: TMC125VIR2038
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A Clinical Trial Comparing the Tolerability of Etravirine to Efavirenz in Combination With 2 Nucleoside/Nucleotide Reverse Transcriptase Inhibitors in Treatment-naive HIV-1 Infected Patients (SENSE)

This study has been completed.

Sponsor:
Janssen-Cilag International NV

Information provided by (Responsible Party):
Janssen-Cilag International NV

ClinicalTrials.gov Identifier:
NCT00903682

First received: May 14, 2009
Last updated: January 7, 2013
Last verified: January 2013
History of Changes

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

Results First Received: February 10, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Conditions:	HIV Infection HIV Acquired Immunodeficiency Syndrome
Interventions:	Drug: etravirine (ETR, TMC125) Drug: efavirenz (EFV)

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
No text entered.

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
Etravirine	Etravirine (ETR TMC125) 400mg once daily (4x100mg tablet) + 2 NRTI + 1 EFV placebo tablet for 48 weeks
Efavirenz	Efavirenz (EFV) 600mg once daily (1x600mg tablet) + 2 NRTIs + 4 ETR placebo tablets for 48 weeks

Participant Flow: Overall Study

	Etravirine	Efavirenz

STARTED	**79**	**78**
COMPLETED	**63**	**63**
NOT COMPLETED	**16**	**15**
Adverse Event	**6**	**13**
Lost to Follow-up	**1**	**0**
Withdrawal by Subject	**5**	**0**
Pregnancy	**0**	**1**
Subject Reached A Virologic Endpoint	**1**	**1**
Subject Non-Compliant	**1**	**0**
Patient Couldn't Come For The Visit Due	**1**	**0**
For Resistent Profile (Excl Crit 2 Met)	**1**	**0**

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
Etravirine	ETR 400mg once daily (4x100mg tablet) + 2 NRTIs + 1 EFV placebo tablet for 48 weeks
Efavirenz	EFV 600mg once daily (1x600mg tablet) + 2 NRTIs + 4 ETR placebo tablets for 48 weeks
Total	Total of all reporting groups

Baseline Measures

	Etravirine	Efavirenz	Total
Number of Participants [units: participants]	**79**	**78**	**157**
Age [units: participants]			
<=18 years	**1**	**0**	**1**
Between 18 and 65 years	**78**	**77**	**155**
>=65 years	**0**	**1**	**1**
Age [units: years] Mean (Standard Deviation)	**37.7 (9.52)**	**37.6 (9.82)**	**37.6 (9.64)**
Gender [units: participants]			
Female	**12**	**18**	**30**
Male	**67**	**60**	**127**
Region of Enrollment [units: participants]			
Austria	**3**	**4**	**7**

Denmark	**0**	**2**	**2**
France	**9**	**9**	**18**
Germany	**16**	**13**	**29**
Hungary	**5**	**3**	**8**
Israel	**4**	**5**	**9**
Italy	**9**	**6**	**15**
Romania	**6**	**10**	**16**
Russia	**9**	**8**	**17**
Spain	**12**	**9**	**21**
Switzerland	**1**	**3**	**4**
UK	**5**	**6**	**11**

Outcome Measures

Hide All Outcome Measures

1. Primary: Proportion of Patients With at Least 1 Treatment-emergent Grade 1-4 Central Nervous System or Psychiatric Adverse Event [Time Frame: between baseline and 12 weeks]

Measure Type	Primary
Measure Title	Proportion of Patients With at Least 1 Treatment-emergent Grade 1-4 Central Nervous System or Psychiatric Adverse Event
Measure Description	Proportion of patients with at least 1 treatment-emergent Grade 1-4 Central Nervous System or psychiatric Adverse Event, observed between Baseline through Week 12 and judged by investigator to be at least possibly related to the study drug in ETR group versus EFV group. All Adverse Events were graded according to the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (“DAIDS AE grading table”). Grade 1-4 covers all severities.
Time Frame	between baseline and 12 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.
The intent-to-treat (ITT) population has been defined as the set of all patients who were randomized and who have taken at least one dose of trial medication, regardless of their compliance with the protocol.

Reporting Groups

	Description
Etravirine	Etravirine (ETR, TMC125) 400mg once daily (4x100mg tablet) + 2 non-nucleoside reverse transcriptase inhibitors (NRTIs) + 1 Efavirenz (EFV) placebo tablet for 48 weeks
Efavirenz	Efavirenz (EFV) 600mg once daily (1x600mg tablet) + 2 NRTIs + 4 ETR placebo tablets for 48 weeks

Measured Values

	Etravirine	**Efavirenz**
Number of Participants Analyzed [units: participants]	**79**	**78**
Proportion of Patients With at Least 1 Treatment-emergent Grade 1-4 Central Nervous System or Psychiatric Adverse Event	**16.5**	**46.2**

[units: percentage of patients]		

Statistical Analysis 1 for Proportion of Patients With at Least 1 Treatment-emergent Grade 1-4 Central Nervous System or Psychiatric Adverse Event

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The hypothesis is that the proportion of patients with at least 1 treatment-emergent Grade 1-4 neuropsychiatric adverse event, observed between Baseline through Week 12 and judged to be at least possibly drug-related, is significantly lower in the ETR arm than in the EFV arm. Assuming a significance level of 5%, a sample size of 75 subjects per arm would provide over 90% power to detect a 29% difference in treatment-emergent, drug-related Grade 1-4 neuropsychiatric adverse events.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

2. Secondary: Antiviral Activity of ETR vs. EFV [Time Frame: between baseline and week 48]

Measure Type	Secondary
Measure Title	Antiviral Activity of ETR vs. EFV
Measure Description	The proportion of patients with confirmed plasma viral load <50 copies/mL at Week 48 as assessed by Time to Loss of Virologic Response (TLOVR)
Time Frame	between 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.
ITT: the set of all randomized patients who have taken at least 1 dose of trial medication, regardless of their compliance with the protocol.

Reporting Groups

	Description
Etravirine	Etravirine (ETR, TMC125) 400mg once daily (4x100mg tablet) + 2 non-nucleoside reverse transcriptase inhibitors (NRTIs) + 1 Efavirenz (EFV) placebo tablet for 48 weeks
Efavirenz	Efavirenz (EFV) 600mg once daily (1x600mg tablet) + 2 NRTIs + 4 ETR placebo tablets for 48 weeks

Measured Values

	Etravirine	**Efavirenz**
Number of Participants Analyzed [units: participants]	**79**	**78**
Antiviral Activity of ETR vs. EFV [units: Number of participants]	**60**	**58**

Statistical Analysis 1 for Antiviral Activity of ETR vs. EFV

Groups [1]	All groups
Difference in proportion of response [2]	1.61
95% Confidence Interval	-12.00 to 15.23

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Difference in proportion of response ETR minus EFV

3. Secondary: Antiviral Activity of ETR vs. EFV [Time Frame: between baseline and week 48]

Measure Type	Secondary
Measure Title	Antiviral Activity of ETR vs. EFV
Measure Description	The proportion of patients with confirmed plasma viral load <200 copies/mL at Week 48 as assessed by Time to Loss of Virologic Response (TLOVR)
Time Frame	between 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.
ITT: the set of all randomized patients who have taken at least 1 dose of trial medication, regardless of their compliance with the protocol.

Reporting Groups

	Description
Etravirine	Etravirine (ETR, TMC125) 400mg once daily (4x100mg tablet) + 2 non-nucleoside reverse transcriptase inhibitors (NRTIs) + 1 Efavirenz (EFV) placebo tablet for 48 weeks
Efavirenz	Efavirenz (EFV) 600mg once daily (1x600mg tablet) + 2 NRTIs + 4 ETR placebo tablets for 48 weeks

Measured Values

	Etravirine	**Efavirenz**
Number of Participants Analyzed [units: participants]	**79**	**78**
Antiviral Activity of ETR vs. EFV [units: Number of participants]	**64**	**62**

No statistical analysis provided for Antiviral Activity of ETR vs. EFV

4. Secondary: Mean Change From Baseline in Neuropsychiatric and Total Tolerabililty Score [Time Frame: between baseline and week 48]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Neuropsychiatric and Total Tolerabililty Score
Measure Description	The HIV Patient Symptoms Profile measures the tolerability of HIV treatment from the patient's perspective, using 14 concept scales in maximum 84 questions. The response options include a "no" or "yes" answer to "Did symptom

	occur?". If "yes", there is a problem scale which ranges from 1 = "I had this symptom and it was not a problem" to 5 = "I had this symptom and it was a severe problem". A neuropsychiatric tolerability score is composed as the sum of 21 items and ranges from 0 (best) to 105 (worse). A total Tolerability score (ie, the sum of all items) ranges from 0 (best) to 420 (worse)
Time Frame	between 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.
ITT: the set of all randomized patients who have taken at least 1 dose of trial medication, regardless of their compliance with the protocol.

Reporting Groups

	Description
Etravirine	Etravirine (ETR, TMC125) 400mg once daily (4x100mg tablet) + 2 non-nucleoside reverse transcriptase inhibitors (NRTIs) + 1 Efavirenz (EFV) placebo tablet for 48 weeks
Efavirenz	Efavirenz (EFV) 600mg once daily (1x600mg tablet) + 2 NRTIs + 4 ETR placebo tablets for 48 weeks

Measured Values

	Etravirine	**Efavirenz**
Number of Participants Analyzed [units: participants]	**75**	**74**
Mean Change From Baseline in Neuropsychiatric and Total Tolerabililty Score [units: points on a scale] Mean (Standard Error)		
Total Tolerability Score	**-0.04 (0.03)**	**-0.01 (0.04)**
Neuropsychiatric Tolerability Score	**-0.04 (0.06)**	**-0.07 (0.07)**

No statistical analysis provided for Mean Change From Baseline in Neuropsychiatric and Total Tolerabililty Score

5. Secondary: Neuropsychiatric Adverse Events by Week 48 [Time Frame: from baseline to week 48]

Measure Type	Secondary
Measure Title	Neuropsychiatric Adverse Events by Week 48
Measure Description	The percentage of patients with at least 1 treatment emergent Grade 1 -4 neurologic or psychiatric adverse event, judged by the investigator to be at least possibly related to the study drug.
Time Frame	from baseline to 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.
ITT: the set of all randomized patients who have taken at least 1 dose of trial medication, regardless of their compliance with the protocol.

Reporting Groups

	Description
Etravirine	Etravirine (ETR, TMC125) 400mg once daily (4x100mg tablet) + 2 non-nucleoside reverse transcriptase inhibitors (NRTIs) + 1 Efavirenz (EFV) placebo tablet for 48 weeks

Efavirenz	Efavirenz (EFV) 600mg once daily (1x600mg tablet) + 2 NRTIs + 4 ETR placebo tablets for 48 weeks

Measured Values

	Etravirine	Efavirenz
Number of Participants Analyzed [units: participants]	**79**	**78**
Neuropsychiatric Adverse Events by Week 48 [units: percentage of patients]	**20.3**	**52.6**

No statistical analysis provided for Neuropsychiatric Adverse Events by Week 48

6. Secondary: Mean Change From Baseline in CD4+ Cell Count [Time Frame: at baseline and week 2, 6, 12, 24, 36 and 48]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CD4+ Cell Count
Measure Description	The mean change in CD4+ cell count from baseline was calculated with a last observation carried forward method; i.e. the last observed value was carried forward, irrespective of the reason for discontinuation.
Time Frame	at baseline and week 2, 6, 12, 24, 36 and 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.
ITT: the set of all randomized patients who have taken at least 1 dose of trial medication, regardless of their compliance with the protocol

Reporting Groups

	Description
Etravirine	Etravirine (ETR, TMC125) 400mg once daily (4x100mg tablet) + 2 non-nucleoside reverse transcriptase inhibitors (NRTIs) + 1 Efavirenz (EFV) placebo tablet for 48 weeks
Efavirenz	Efavirenz (EFV) 600mg once daily (1x600mg tablet) + 2 NRTIs + 4 ETR placebo tablets for 48 weeks

Measured Values

	Etravirine	Efavirenz
Number of Participants Analyzed [units: participants]	**74**	**74**
Mean Change From Baseline in CD4+ Cell Count [units: number of cells/L (x10^6)] Mean (Standard Error)		
Week 2	**69.96 (9.82)**	**72.45 (11.33)**
Week 6	**128.14 (13.19)**	**121.62 (13.96)**
Week 12	**143.24 (13.56)**	**151.46 (16.68)**
Week 24	**182.01 (16.48)**	**174.08 (14.85)**
Week 36	**213.45 (19.11)**	**180.18 (15.12)**
Week 48	**205.11 (20.07)**	**221.39 (18.31)**

No statistical analysis provided for Mean Change From Baseline in CD4+ Cell Count

7. Secondary: Resistance Determinations [Time Frame: at baseline and all subsequent visits until week 48 in case if virologic failure]

Measure Type	Secondary
Measure Title	Resistance Determinations
Measure Description	The evolution of viral genotype and phenotype was assessed by the number of patients with resistance-associated mutations emerging at the endpoint. A mutation was considered emerging if it was present at endpoint and not present at baseline or any pre-baseline assessment. (NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; RAM = resistance-associated mutation, IAS-USA = International AIDS Society - USA)
Time Frame	at baseline and all subsequent visits until week 48 in case if virologic failure
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.
ITT: the set of all randomized patients who have taken at least 1 dose of trial medication, regardless of their compliance with the protocol

Reporting Groups

	Description
Etravirine	Etravirine (ETR, TMC125) 400mg once daily (4x100mg tablet) + 2 non-nucleoside reverse transcriptase inhibitors (NRTIs) + 1 Efavirenz (EFV) placebo tablet for 48 weeks
Efavirenz	Efavirenz (EFV) 600mg once daily (1x600mg tablet) + 2 NRTIs + 4 ETR placebo tablets for 48 weeks

Measured Values

	Etravirine	**Efavirenz**
Number of Participants Analyzed [units: participants]	**79**	**78**
Resistance Determinations [units: number of participants]		
>= 1 successful genotype after baseline	**11**	**9**
>= 1 IAS-USA NRTI RAMs	**0**	**2**
>= 1 NRTI Surveillance Drug Resistance Mutation	**0**	**2**
>= 1 NNRTI RAMs	**2**	**3**
no NRTI or NNRTI RAMs	**9**	**6**

No statistical analysis provided for Resistance Determinations

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events represented here were collected between signing of informed consent and the visit at week 48.
Additional Description	No text entered.

Reporting Groups

	Description
Etravirine	ETR 400mg once daily (4x100mg tablet) + 2 NRTIs + 1 EFV placebo tablet for 48 weeks

Efavirenz	EFV 600mg once daily (1x600mg tablet) + 2 NRTIs + 4 ETR placebo tablets for 48 weeks

Serious Adverse Events

	Etravirine	Efavirenz
Total, serious adverse events		
# participants affected / at risk	**11/79 (13.92%)**	**6/78 (7.69%)**
Blood and lymphatic system disorders		
Anaemia [*1]		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Eye disorders		
Conjunctivitis [*1]		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Gastrointestinal disorders		
Anal Fissure [*1]		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Stomatitis [*1]		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
General disorders		
Pyrexia [*1]		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Hepatobiliary disorders		
Cholelithiasis [*1]		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Infections and infestations		
Pneumonia [*1]		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Pulmonary Tuberculosis [*1]		
# participants affected / at risk	**0/79 (0.00%)**	**1/78 (1.28%)**
Anal Abscess [*1]		
# participants affected / at risk	**0/79 (0.00%)**	**1/78 (1.28%)**
Anogenital Warts [*1]		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Secondary Syphilis [*1]		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Investigations		
Alanine Aminotransferase Increased [*1]		
# participants affected / at risk	**1/79 (1.27%)**	**1/78 (1.28%)**
Aspartate Aminotransferase Increased [*1]		
# participants affected / at risk	**0/79 (0.00%)**	**1/78 (1.28%)**
Musculoskeletal and connective tissue disorders		
Joint Ankylosis [*1]		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		

Basal Cell Carcinoma * 1		
# participants affected / at risk	**0/79 (0.00%)**	**1/78 (1.28%)**
Non-Hodgkin's Lymphoma * 1		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Squamous Cell Carcinoma * 1		
# participants affected / at risk	**0/79 (0.00%)**	**1/78 (1.28%)**
Benign Ovarian Tumour * 1		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Lymphoma * 1		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Uterine Leiomyoma * 1		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Renal and urinary disorders		
Urethral Stenosis * 1		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Pneumothorax * 1		
# participants affected / at risk	**0/79 (0.00%)**	**1/78 (1.28%)**
Laryngeal Inflammation * 1		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Skin and subcutaneous tissue disorders		
Rash * 1		
# participants affected / at risk	**1/79 (1.27%)**	**0/78 (0.00%)**
Surgical and medical procedures		
Abortion Induced * 1		
# participants affected / at risk	**0/79 (0.00%)**	**1/78 (1.28%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 12.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events represented here were collected between signing of informed consent and the visit at week 48.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Etravirine	ETR 400mg once daily (4x100mg tablet) + 2 NRTIs + 1 EFV placebo tablet for 48 weeks
Efavirenz	EFV 600mg once daily (1x600mg tablet) + 2 NRTIs + 4 ETR placebo tablets for 48 weeks

Other Adverse Events

	Etravirine	Efavirenz
Total, other (not including serious) adverse events		
# participants affected / at risk	**54/79 (68.35%)**	**62/78 (79.49%)**
Blood and lymphatic system disorders		
Anaemia [*1]		
# participants affected / at risk	**1/79 (1.27%)**	**4/78 (5.13%)**
Ear and labyrinth disorders		
Vertigo [*1]		
# participants affected / at risk	**2/79 (2.53%)**	**4/78 (5.13%)**
Gastrointestinal disorders		
Diarrhoea [*1]		
# participants affected / at risk	**8/79 (10.13%)**	**9/78 (11.54%)**
Nausea [*1]		
# participants affected / at risk	**7/79 (8.86%)**	**13/78 (16.67%)**
Vomiting [*1]		
# participants affected / at risk	**2/79 (2.53%)**	**6/78 (7.69%)**
Dyspepsia [*1]		
# participants affected / at risk	**6/79 (7.59%)**	**3/78 (3.85%)**
General disorders		
Asthenia [*1]		
# participants affected / at risk	**3/79 (3.80%)**	**5/78 (6.41%)**
Pyrexia [*1]		
# participants affected / at risk	**5/79 (6.33%)**	**5/78 (6.41%)**
Fatigue [*1]		
# participants affected / at risk	**5/79 (6.33%)**	**6/78 (7.69%)**
Infections and infestations		
Influenza [*1]		
# participants affected / at risk	**6/79 (7.59%)**	**1/78 (1.28%)**
Nasopharyngitis [*1]		
# participants affected / at risk	**17/79 (21.52%)**	**6/78 (7.69%)**
Bronchitis [*1]		
# participants affected / at risk	**5/79 (6.33%)**	**5/78 (6.41%)**
Pharyngitis [*1]		
# participants affected / at risk	**4/79 (5.06%)**	**2/78 (2.56%)**
Metabolism and nutrition disorders		
Hypercholesterolaemia [*1]		
# participants affected / at risk	**3/79 (3.80%)**	**7/78 (8.97%)**
Hypertriglyceridaemia [*1]		
# participants affected / at risk	**2/79 (2.53%)**	**4/78 (5.13%)**
Musculoskeletal and connective tissue disorders		
Back Pain [*1]		
# participants affected / at risk	**7/79 (8.86%)**	**3/78 (3.85%)**
Nervous system disorders		

Dizziness * 1		
# participants affected / at risk	**3/79 (3.80%)**	**17/78 (21.79%)**
Headache * 1		
# participants affected / at risk	**13/79 (16.46%)**	**11/78 (14.10%)**
Somnolence * 1		
# participants affected / at risk	**2/79 (2.53%)**	**5/78 (6.41%)**
Disturbance in Attention * 1		
# participants affected / at risk	**1/79 (1.27%)**	**4/78 (5.13%)**
Psychiatric disorders		
Abnormal Dreams * 1		
# participants affected / at risk	**2/79 (2.53%)**	**9/78 (11.54%)**
Insomnia * 1		
# participants affected / at risk	**2/79 (2.53%)**	**8/78 (10.26%)**
Nightmare * 1		
# participants affected / at risk	**3/79 (3.80%)**	**7/78 (8.97%)**
Sleep Disorder * 1		
# participants affected / at risk	**4/79 (5.06%)**	**8/78 (10.26%)**
Anxiety * 1		
# participants affected / at risk	**1/79 (1.27%)**	**4/78 (5.13%)**
Depression * 1		
# participants affected / at risk	**1/79 (1.27%)**	**5/78 (6.41%)**
Skin and subcutaneous tissue disorders		
Pruritus * 1		
# participants affected / at risk	**5/79 (6.33%)**	**7/78 (8.97%)**
Rash * 1		
# participants affected / at risk	**5/79 (6.33%)**	**2/78 (2.56%)**
Vascular disorders		
Hot Flush * 1		
# participants affected / at risk	**0/79 (0.00%)**	**4/78 (5.13%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 12.0

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
No text entered.

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:** A copy of the manuscript must be provided to the Sponsor for review at least 60 days prior to submission for publication or presentation. No paper that incorporates Confidential Information will be submitted for publication without Sponsor's prior written consent. If requested in writing, such publication will be withheld for up to an additional 60 calendar days. A publication from the individual Study site data will not be published until the combined results have been published.

Results Point of Contact:

Name/Title: EMEA Medical Affairs Director Virology
Organization: Janssen-Cilag EMEA
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Publications of Results:

Nelson M, Stellbrink HJ, Podzamczer D, Banhegyi D, Gazzard B, Hill A, van Delft Y, Vingerhoets J, Stark T, Marks S. A comparison of neuropsychiatric adverse events during 12 weeks of treatment with etravirine and efavirenz in a treatment-naive, HIV-1-infected population. AIDS. 2011 Jan 28;25(3):335-40. doi: 10.1097/QAD.0b013e3283416873.

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Fätkenheuer G, Duvivier C, Rieger A, Durant J, Rey D, Schmidt W, Hill A, van Delft Y, Marks S; SENSE Study Team. Lipid profiles for etravirine versus efavirenz in treatment-naive patients in the randomized, double-blind SENSE trial. J Antimicrob Chemother. 2012 Mar;67(3):685-90. doi: 10.1093/jac/dkr533. Epub 2011 Dec 29.

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