MK-5442 in the Treatment of Osteoporosis in Postmenopausal Women Previously Treated With an Oral Bisphosphonate (MK-5442-012)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00996801

First received: October 15, 2009
Last updated: January 21, 2016
Last verified: January 2016
History of Changes

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Purpose

This study seeks to demonstrate that additional gain in bone mineral density (BMD) can be achieved by switching to MK-5442 from an oral bisphosphonate in participants who have been receiving oral bisphosphonate therapy for at least 3 years.

Condition	Intervention	Phase
Osteoporosis Postmenopausal Osteoporosis	Drug: MK-5442 Drug: Placebo to MK-5442 Drug: Alendronate Sodium Drug: Vitamin D3 Drug: Calcium carbonate Drug: Placebo to Alendronate	Phase 2

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 Phase IIb, Randomized, Double-Blind, Placebo- and Active-Controlled, Dose-Range-Finding Study to Evaluate the Effects of MK-5442 on Bone Mineral Density (BMD) in the Treatment of Osteoporosis in Postmenopausal Women Previously Treated With an Oral Bisphosphonate

Resource links provided by NLM:

MedlinePlus related topics: Bone Density Calcium Minerals Osteoporosis Vitamin D

Drug Information available for: Cholecalciferol Calcium Gluconate Calcium carbonate Vitamin D Alendronate sodium

U.S. FDA Resources

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

Primary Outcome Measures:

- Least Squares Mean Percent Change From Baseline To Month 12 in Lumbar Spine Areal Bone Mineral Density (BMD) [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  Areal bone mineral density (BMD) was measured using dual-energy X-ray absorptiometry (DXA) scanning technology. Scanning is performed with two X-ray beams with different energy levels which are aimed at the participant's bones. When soft tissue absorption is subtracted out, the BMD is determined from the absorption of each beam by bone. BMD = BMC / W, where BMD = bone mineral density in g/cm^2, BMC = bone mineral content in g/cm, and W = width at the scanned line in cm

- Number of Participants With Trough Serum Calcium Level Exceeding Predefined Limits At Least Once [Time Frame: Baseline through Month 12] [Designated as safety issue: Yes]

  Normal serum calcium level is 8-10 mg/dL (2-2.5 mmol/L) with some interlaboratory variation in the reference range, and hypercalcemia is defined as a serum calcium level greater than 10.5 mg/dL (>2.5 mmol/L). Based on these references, ≥10.6 mg/dL was predefined in this study as the cut-off for the normal limits of change. Participants with at least a one calcium level value ≥10.6 mg/dL were considered as having a "Tier 1" adverse event (AE). A Tier 1 AE was an AE of special interest identified a priori that could be used for inferential testing for statistical significance for between-group comparisons.

- Number of Participants With Trough Albumin-Corrected Calcium Level Exceeding Predefined Limits At Least Once [Time Frame: Baseline through Month 12] [Designated as safety issue: Yes]

  Albumin-Corrected Calcium = ([4 - plasma albumin in g/dL] × 0.8 + serum calcium). ≥10.6 mg/dL was predefined in this study as the cut-off for the normal limits of change. Participants with at least one albumin-corrected calcium level value ≥10.6 mg/dL were considered as having a "Tier 1" AE (an AE of special interest identified a priori that could be used for inferential testing for statistical significance for between-group comparisons).

- Number of Participants With Predefined Tier 1 Adverse Events [Time Frame: Baseline through Month 12] [Designated as safety issue: Yes]

  Osteonecrosis of the jaw (ONJ), kidney stones, and bone neoplasms were predefined Tier-1 AEs in the study (an AE of special interest identified a priori that could be used for inferential testing for statistical significance for between-group comparisons).

Secondary Outcome Measures:

- Least Squares Mean Percent Change From Baseline to Month 12 in Total Hip Areal BMD [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  Areal bone mineral density (BMD) was measured using DXA scanning technology. Scanning is performed with two X-ray beams with different energy levels which are aimed at the participant's bones. When soft tissue absorption is subtracted out, the BMD is determined from the absorption of each beam by bone. BMD = BMC / W, where BMD = bone mineral density in g/cm^2, BMC = bone mineral content in g/cm, and W = width at the scanned line in cm

- Least Squares Mean Percent Change From Baseline to Month 12 in Femoral Neck Areal BMD [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  Areal bone mineral density (BMD) was measured using DXA scanning technology. Scanning is performed with two X-ray beams with different energy levels which are aimed at the participant's bones. When soft tissue absorption is subtracted out, the BMD is determined from the absorption of each beam by bone. BMD = BMC / W, where BMD = bone mineral density in g/cm^2, BMC = bone mineral content in g/cm, and W = width at the scanned line in cm

- Least Squares Mean Percent Change From Baseline to Month 12 in Trochanter Areal BMD [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  Areal bone mineral density (BMD) was measured using DXA scanning technology. Scanning is performed with two X-ray beams with different energy levels which are aimed at the participant's bones. When soft tissue absorption is subtracted out, the BMD is determined from the absorption of each beam by bone. BMD = BMC / W, where BMD = bone mineral density in g/cm^2, BMC = bone mineral content in g/cm, and W = width at the scanned line in cm

- Least Squares Mean Percent Change From Baseline to Month 12 in Total Body Areal BMD [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  Areal bone mineral density (BMD) was measured using DXA scanning technology. Scanning is performed with two X-ray beams with different

energy levels which are aimed at the participant's bones. When soft tissue absorption is subtracted out, the BMD is determined from the absorption of each beam by bone. BMD = BMC / W, where BMD = bone mineral density in g/cm^2, BMC = bone mineral content in g/cm, and W = width at the scanned line in cm

- Least Squares Mean Percent Change From Baseline to Month 12 in 1/3 Distal Forearm Areal BMD [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  Areal bone mineral density (BMD) was measured using DXA scanning technology. Scanning is performed with two X-ray beams with different energy levels which are aimed at the participant's bones. When soft tissue absorption is subtracted out, the BMD is determined from the absorption of each beam by bone. BMD = BMC / W, where BMD = bone mineral density in g/cm^2, BMC = bone mineral content in g/cm, and W = width at the scanned line in cm

- Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD (vBMD) of the Lumbar Spine [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  vBMD was measured using quantitative computed tomography (QCT) in order to assess bone strength. Quantitative computed tomography is a three-dimensional non-projectional technique that quantifies trabecular and cortical BMD in the lumbar spine and hip as a true volumetric mineral density in g/cm^3.

- Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD of the Hip [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  vBMD was measured using QCT in order to assess bone strength. QCT is a three-dimensional non-projectional technique that quantifies trabecular and cortical BMD in the lumbar spine and hip as a true volumetric mineral density in g/cm^3.

- Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Lumbar Spine [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  vBMD was measured using QCT in order to assess bone strength. QCT is a three-dimensional non-projectional technique that quantifies trabecular and cortical BMD in the lumbar spine and hip as a true volumetric mineral density in g/cm^3.

- Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Hip [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  vBMD was measured using QCT in order to assess bone strength. QCT is a three-dimensional non-projectional technique that quantifies trabecular and cortical BMD in the lumbar spine and hip as a true volumetric mineral density in g/cm^3.

- Least Squares Mean Percent Change From Baseline to Month 12 in Urinary-N Telopeptides of Type 1 Collagen (u-NTx) [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  Urinary, type I collagen, crosslinked N-telopeptide (uNTx) is a biomarker used to measure the rate of bone turnover found in urine. uNTx was expressed in units of nanomoles (nM) per bone collagen equivalents (BCE) per millimoles of creatinine (Cr) or nM/BCE/mM Cr

- Least Squares Mean Percent Change From Baseline to Month 12 in Serum C-Terminal Propeptide of Type 1 Collagen (s-CTx) [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  C-Terminal Telopeptide Collagen I is used as a serum-marker of bone resorption in the assessment of osteoporosis and in measured in units of nanograms (n)/milliliter (ml).

- Least Squares Mean Percent Change From Baseline to Month 12 in Serum N-Terminal Propeptide (s-P1NP) [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  s-P1NP is a sensitive marker of bone formation rate in the assessment of osteoporosis and is measured in units of ng/ml.

- Least Squares Mean Percent Change From Baseline to Month 12 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP) [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  Bone Specific Alkaline Phosphatase is a biomarker of bone formation and is measured in units of µg/L.

- Least Squares Mean Percent Change From Baseline to Month 12 in Serum Osteocalcin [Time Frame: Baseline and Month 12] [Designated as safety issue: No]

  Serum osteocalcin is a biomarker of bone formation and is measured using units of nanograms (ng) / milliliter (mL).

Enrollment: 526

Study Start Date: November 2009
Study Completion Date: June 2011
Primary Completion Date: June 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Placebo Comparator: Placebo Participants received either matching placebo to alendronate (administered orally, once-weekly) or matching placebo to MK-5442 (administered orally, once-daily) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.	Drug: Placebo to MK-5442 Matching placebo to MK-5442 taken orally, once-daily, for 12 months Drug: Vitamin D3 Vitamin D3 (cholecalciferol) administered orally, at a dose of 5600 IU (two tablets, 2800 IU each), once-weekly for 12 months Other Name: Cholecalciferol Drug: Calcium carbonate Participants who qualify (those who have a calcium intake of less than 1200 mg/day) will receive oral supplemental calcium carbonate, at a dose of either 400 mg or 500 mg, once-daily, for 12 months Drug: Placebo to Alendronate Placebo to alendronate once-weekly for 12 months
Experimental: MK-5442 5 mg Participants received 5 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.	Drug: MK-5442 MK-5442 tablets (randomized to a dose of 5, 7.5, 10 or 15 mg) taken orally, once-daily, for 12 months Drug: Vitamin D3 Vitamin D3 (cholecalciferol) administered orally, at a dose of 5600 IU (two tablets, 2800 IU each), once-weekly for 12 months Other Name: Cholecalciferol Drug: Calcium carbonate Participants who qualify (those who have a calcium intake of less than 1200 mg/day) will receive oral supplemental calcium carbonate, at a dose of either 400 mg or 500 mg, once-daily, for 12 months Drug: Placebo to Alendronate Placebo to alendronate once-weekly for 12 months
Experimental: MK-5442 7.5 mg Participants received 7.5 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.	Drug: MK-5442 MK-5442 tablets (randomized to a dose of 5, 7.5, 10 or 15 mg) taken orally, once-daily, for 12 months Drug: Vitamin D3 Vitamin D3 (cholecalciferol) administered orally, at a dose of 5600 IU (two tablets, 2800 IU each), once-weekly for 12 months Other Name: Cholecalciferol Drug: Calcium carbonate Participants who qualify (those who have a calcium intake of less than 1200 mg/day) will receive oral supplemental calcium carbonate, at a dose of either 400 mg or 500 mg, once-daily, for 12 months Drug: Placebo to Alendronate Placebo to alendronate once-weekly for 12 months
Experimental: MK-5442 10 mg Participants received 10 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.	Drug: MK-5442 MK-5442 tablets (randomized to a dose of 5, 7.5, 10 or 15 mg) taken orally, once-daily, for 12 months Drug: Vitamin D3 Vitamin D3 (cholecalciferol) administered orally, at a dose of 5600 IU (two tablets, 2800 IU each), once-weekly for 12

	months Other Name: Cholecalciferol Drug: Calcium carbonate Participants who qualify (those who have a calcium intake of less than 1200 mg/day) will receive oral supplemental calcium carbonate, at a dose of either 400 mg or 500 mg, once-daily, for 12 months Drug: Placebo to Alendronate Placebo to alendronate once-weekly for 12 months
Experimental: MK-5442 15 mg Participants received 15 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.	Drug: MK-5442 MK-5442 tablets (randomized to a dose of 5, 7.5, 10 or 15 mg) taken orally, once-daily, for 12 months Drug: Vitamin D3 Vitamin D3 (cholecalciferol) administered orally, at a dose of 5600 IU (two tablets, 2800 IU each), once-weekly for 12 months Other Name: Cholecalciferol Drug: Calcium carbonate Participants who qualify (those who have a calcium intake of less than 1200 mg/day) will receive oral supplemental calcium carbonate, at a dose of either 400 mg or 500 mg, once-daily, for 12 months Drug: Placebo to Alendronate Placebo to alendronate once-weekly for 12 months
Active Comparator: Alendronate 70 mg Participants received 70 mg alendronate (orally, once-weekly) plus matching placebo to MK-5442 (administered orally, once-daily) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.	Drug: Placebo to MK-5442 Matching placebo to MK-5442 taken orally, once-daily, for 12 months Drug: Alendronate Sodium Alendronate tablets 70 mg, taken orally, once-weekly, for 12 months Other Name: FOSAMAX® Drug: Vitamin D3 Vitamin D3 (cholecalciferol) administered orally, at a dose of 5600 IU (two tablets, 2800 IU each), once-weekly for 12 months Other Name: Cholecalciferol Drug: Calcium carbonate Participants who qualify (those who have a calcium intake of less than 1200 mg/day) will receive oral supplemental calcium carbonate, at a dose of either 400 mg or 500 mg, once-daily, for 12 months

Detailed Description:

The study was originally planned for a duration of 2 years and included efficacy analysis of a 15 mg MK-5442 treatment arm. Amendment 1 of the protocol eliminated the 2nd year of the study as well the 15-mg arm. Enrollment into the 15-mg MK-5442 arm was stopped as a result of the amendment and all participants who had been randomly assigned to the MK-5442 15-mg treatment arm were discontinued from the study.

Eligibility

Ages Eligible for Study:	45 Years to 85 Years
Genders Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Taking oral bisphosphonate treatment for osteoporosis for at least 3 of the past 4 years. At present, and for the past 12 months, treated with alendronate

Bone Mineral Density (BMD) T-score that is ≤ -1.5 at one or more of the following anatomic sites; lumbar spine, femoral neck, trochanter, and total hip, AND a BMD T-score at all of these sites that is ≥ -4.0, AND a history of at least one fragility fracture, OR, a BMD T-score that is ≤ -2.5 at one or more of the following anatomic sites; lumbar spine, femoral neck, trochanter, and total hip, AND a BMD T-score at all of these sites that is ≥ -4.0

- Postmenopausal for at least 5 years

Exclusion Criteria:

- Obesity (ie, weight greater than 250 pounds) that prohibits the use of dual-emission X-ray absorptiometry (DXA)
- Received intravenous (IV) bisphosphonates, fluoride treatment at a dose >1 mg/day for more than 2 weeks, strontium, growth hormone, a cathepsin K (CTSK) inhibitor, or a receptor activator of nuclear factor kappa-B ligand (RANKL) inhibitor at any time in the past
- Use of oral bisphosphonates other than alendronate in the last 12 months, parathyroid hormone (PTH) in the last 24 months, cyclosporin for more than 2 weeks in the last 6 months, heparin in the last 2 weeks, or anabolic steroids or glucocorticoids for more than 2 weeks in the past 6 months
- Use of estrogen with or without progestin or a selective estrogen receptor modulator (SERM) in the last 6 months or calcitonin in the last 30 days
- Has used pioglitazone hydrochloride or rosiglitazone hydrochloride in the last 6 months
- Taking more than 10,000 International Units (IU) vitamin A daily or more than 5,000 IU vitamin D daily
- Has had a total thyroidectomy
- History of Paget's disease
- Has human immunodeficiency virus (HIV)
- History of cancer in the last 5 years, except certain skin or cervical cancers
- History of major upper gastrointestinal (GI) mucosal erosive disease
- Unable to adhere to dosing instructions for alendronate in regard to fasting and positioning
- Not ambulatory

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.

No Contacts or Locations Provided

More Information

Publications:

Cosman F, Gilchrist N, McClung M, Foldes J, de Villiers T, Santora A, Leung A, Samanta S, Heyden N, McGinnis JP 2nd, Rosenberg E, Denker AE. A phase 2 study of MK-5442, a calcium-sensing receptor antagonist, in postmenopausal women with osteoporosis after long-term use of oral bisphosphonates. Osteoporos Int. 2016 Jan;27(1):377-86. doi: 10.1007/s00198-015-3392-7. Epub 2015 Nov 10.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00996801 History of Changes
Other Study ID Numbers:	5442-012 2009-014729-18 CTRI/2010/091/000258
Study First Received:	October 15, 2009
Results First Received:	August 31, 2012
Last Updated:	January 21, 2016
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Osteoporosis	Vitamin D
Osteoporosis, Postmenopausal	Vitamins
Bone Diseases	Antacids
Bone Diseases, Metabolic	Bone Density Conservation Agents
Musculoskeletal Diseases	Growth Substances
Alendronate	Micronutrients
Calcium Carbonate	Molecular Mechanisms of Pharmacological Action

Cholecalciferol
Diphosphonates
Ergocalciferols

Pharmacologic Actions
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on May 08, 2016

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MK-5442 in the Treatment of Osteoporosis in Postmenopausal Women Previously Treated With an Oral Bisphosphonate (MK-5442-012)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00996801

First received: October 15, 2009
Last updated: January 21, 2016
Last verified: January 2016
History of Changes

Results First Received: August 31, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Osteoporosis Postmenopausal Osteoporosis
Interventions:	Drug: MK-5442 Drug: Placebo to MK-5442 Drug: Alendronate Sodium Drug: Vitamin D3 Drug: Calcium carbonate Drug: Placebo to Alendronate

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
Placebo	Participants received either matching placebo to alendronate (administered orally, once-weekly) or matching placebo to MK-5442 (administered orally, once-daily) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
MK-5442 5 mg	Participants received 5 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
MK-5442 7.5 mg	Participants received 7.5 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
MK-5442 10 mg	Participants received 10 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
MK-5442 15 mg	Participants received 15 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
Alendronate 70 mg	Participants received 70 mg alendronate (orally, once-weekly) plus matching placebo to MK-5442 (administered orally, once-daily) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.

Participant Flow: Overall Study

	Placebo	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Alendronate 70 mg
STARTED	88	88	88	87	88 [1]	87
COMPLETED	68	72	65	56	0	68
NOT COMPLETED	20	16	23	31	88	19
Adverse Event	6	4	12	17	31	3
Lack of Efficacy	3	0	1	3	0	1
Lost to Follow-up	0	0	0	3	3	2
Physician Decision	0	0	0	1	0	0
Progressive Disease	0	1	0	0	0	0
Protocol Violation	3	4	1	2	3	4
Study Terminated by Sponsor	0	1	0	0	46	0
Withdrawal by Subject	8	6	9	5	5	9

[1] 15-mg arm was discontinued as a result of Protocol Amendment 1.

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
Placebo	Participants received either matching placebo to alendronate (administered orally, once-weekly) or matching placebo to MK-5442 (administered orally, once-daily) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
MK-5442 5 mg	Participants received 5 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
MK-5442 7.5 mg	Participants received 7.5 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
MK-5442 10 mg	Participants received 10 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
MK-5442 15 mg	Participants received 15 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
Alendronate 70 mg	Participants received 70 mg alendronate (orally, once-weekly) plus matching placebo to MK-5442 (administered orally, once-daily) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
Total	Total of all reporting groups

Baseline Measures

	Placebo	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**MK-5442 15 mg**	**Alendronate 70 mg**	**Total**
Number of Participants [units: participants]	**88**	**88**	**88**	**87**	**88**	**87**	**526**
Age [units: Years] Mean (Standard Deviation)	**67.8 (7.8)**	**66.5 (8.8)**	**67.3 (7.1)**	**68.2 (6.9)**	**68.1 (7.4)**	**66.9 (7.5)**	**67.5 (7.6)**
Gender [units: participants]							
Female	**88**	**88**	**88**	**87**	**88**	**87**	**526**
Male	**0**	**0**	**0**	**0**	**0**	**0**	**0**

Outcome Measures

Hide All Outcome Measures

1. Primary: Least Squares Mean Percent Change From Baseline To Month 12 in Lumbar Spine Areal Bone Mineral Density (BMD) [Time Frame: Baseline and Month 12]

Measure Type	Primary
Measure Title	Least Squares Mean Percent Change From Baseline To Month 12 in Lumbar Spine Areal Bone Mineral Density (BMD)
Measure Description	Areal bone mineral density (BMD) was measured using dual-energy X-ray absorptiometry (DXA) scanning technology. Scanning is performed with two X-ray beams with different energy levels which are aimed at the participant's bones. When soft tissue absorption is subtracted out, the BMD is determined from the absorption of each beam by bone. BMD = BMC / W, where BMD = bone mineral density in g/cm^2, BMC = bone mineral content in g/cm, and W = width at the scanned line in cm
Time Frame	Baseline and Month 12
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.
Full Analysis Set (FAS): participants who received at least one dose of study treatment, had at least one post-randomization observation, and who had baseline data. The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	**MK-5442 5 mg**	**MK-5442 7.5mg**	**MK-5442 10 mg**	**Alendronate 70 mg**
Number of Participants Analyzed [units: participants]	**81**	**82**	**79**	**78**	**79**
Least Squares Mean Percent Change From Baseline To Month 12 in Lumbar Spine Areal Bone Mineral Density (BMD) **[units: percent change]** **Least Squares Mean (95% Confidence Interval)**	**-0.36 (-1.37 to 0.66)**	**-0.67 (-1.67 to 0.33)**	**-0.52 (-1.56 to 0.52)**	**-0.53 (-1.61 to 0.56)**	**1.29 (0.25 to 2.33)**

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline To Month 12 in Lumbar Spine Areal Bone Mineral Density (BMD)

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg

Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.012
Difference in Least Squares Means [4]	-1.96
95% Confidence Interval	-3.58 to -0.35

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline To Month 12 in Lumbar Spine Areal Bone Mineral Density (BMD)

Groups [1]	MK-5442 7.5mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.019
Difference in Least Squares Means [4]	-1.81
95% Confidence Interval	-3.37 to -0.25

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline To Month 12 in Lumbar Spine Areal Bone Mineral Density (BMD)

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.019
Difference in Least Squares Means [4]	-1.82

95% Confidence Interval	-3.23 to -0.41

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

2. Primary: Number of Participants With Trough Serum Calcium Level Exceeding Predefined Limits At Least Once [Time Frame: Baseline through Month 12]

Measure Type	Primary
Measure Title	Number of Participants With Trough Serum Calcium Level Exceeding Predefined Limits At Least Once
Measure Description	Normal serum calcium level is 8-10 mg/dL (2-2.5 mmol/L) with some interlaboratory variation in the reference range, and hypercalcemia is defined as a serum calcium level greater than 10.5 mg/dL (>2.5 mmol/L). Based on these references, ≥10.6 mg/dL was predefined in this study as the cut-off for the normal limits of change. Participants with at least a one calcium level value ≥10.6 mg/dL were considered as having a "Tier 1" adverse event (AE). A Tier 1 AE was an AE of special interest identified a priori that could be used for inferential testing for statistical significance for between-group comparisons.
Time Frame	Baseline through Month 12
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 as Treated (APaT): all randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 15 mg	Participants were initially randomized to receive oral, once-daily MK-5442 15 mg and once-weekly matching placebo to alendronate for 12 months.

	The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	**88**	**87**	**88**	**87**	**88**	**84**
Number of Participants With Trough Serum Calcium Level Exceeding Predefined Limits At Least Once [units: Participants]						
≥10.6 ng/mL	**3**	**16**	**19**	**27**	**39**	**7**
≥11.1 ng/mL	**1**	**1**	**4**	**7**	**19**	**1**
≥12.1 ng/mL	**0**	**0**	**0**	**1**	**1**	**0**

No statistical analysis provided for Number of Participants With Trough Serum Calcium Level Exceeding Predefined Limits At Least Once

3. Primary: Number of Participants With Trough Albumin-Corrected Calcium Level Exceeding Predefined Limits At Least Once [Time Frame: Baseline through Month 12]

Measure Type	Primary
Measure Title	Number of Participants With Trough Albumin-Corrected Calcium Level Exceeding Predefined Limits At Least Once
Measure Description	Albumin-Corrected Calcium = ([4 - plasma albumin in g/dL] × 0.8 + serum calcium). ≥10.6 mg/dL was predefined in this study as the cut-off for the normal limits of change. Participants with at least one albumin-corrected calcium level value ≥10.6 mg/dL were considered as having a "Tier 1" AE (an AE of special interest identified a priori that could be used for inferential testing for statistical significance for between-group comparisons).
Time Frame	Baseline through Month 12
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 as Treated (APaT): all randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.

MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 15 mg	Participants were initially randomized to receive oral, once-daily MK-5442 15 mg and once-weekly matching placebo to alendronate for 12 months. The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	**88**	**87**	**88**	**87**	**88**	**84**
Number of Participants With Trough Albumin-Corrected Calcium Level Exceeding Predefined Limits At Least Once [units: Participants]						
≥10.6 ng/mL	**1**	**3**	**7**	**13**	**28**	**2**
≥11.1 ng/mL	**1**	**0**	**1**	**3**	**9**	**0**
≥12.1 ng/mL	**0**	**0**	**0**	**1**	**0**	**0**

No statistical analysis provided for Number of Participants With Trough Albumin-Corrected Calcium Level Exceeding Predefined Limits At Least Once

4. Primary: Number of Participants With Predefined Tier 1 Adverse Events [Time Frame: Baseline through Month 12]

Measure Type	Primary
Measure Title	Number of Participants With Predefined Tier 1 Adverse Events
Measure Description	Osteonecrosis of the jaw (ONJ), kidney stones, and bone neoplasms were predefined Tier-1 AEs in the study (an AE of special interest identified a priori that could be used for inferential testing for statistical significance for between-group comparisons).
Time Frame	Baseline through Month 12
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 as Treated (APaT): all randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.

MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 15 mg	Participants were initially randomized to receive oral, once-daily MK-5442 15 mg and once-weekly matching placebo to alendronate for 12 months. The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	**88**	**87**	**88**	**87**	**88**	**84**
Number of Participants With Predefined Tier 1 Adverse Events [units: Participants]						
Osteonecrosis of the jaw	**0**	**0**	**0**	**0**	**0**	**0**
Kidney stones	**3**	**0**	**0**	**0**	**0**	**1**
Bone neoplasms	**0**	**0**	**0**	**0**	**0**	**0**

No statistical analysis provided for Number of Participants With Predefined Tier 1 Adverse Events

5. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Total Hip Areal BMD [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Total Hip Areal BMD
Measure Description	Areal bone mineral density (BMD) was measured using DXA scanning technology. Scanning is performed with two X-ray beams with different energy levels which are aimed at the participant's bones. When soft tissue absorption is subtracted out, the BMD is determined from the absorption of each beam by bone. BMD = BMC / W, where BMD = bone mineral density in g/cm^2, BMC = bone mineral content in g/cm, and W = width at the scanned line in cm
Time Frame	Baseline and Month 12
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.
Full Analysis Set (FAS): participants who received at least one dose of study treatment, had at least one post-randomization observation, and who had baseline data. The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	**81**	**82**	**79**	**78**	**79**
Least Squares Mean Percent Change From Baseline to Month 12 in Total Hip Areal BMD [units: percent change] Least Squares Mean (95% Confidence Interval)	**-1.44 (-2.24 to -0.65)**	**-2.18 (-2.97 to -1.39)**	**-2.16 (-2.98 to -1.33)**	**-1.66 (-2.52 to -0.80)**	**0.46 (-0.36 to 1.29)**

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in Total Hip Areal BMD

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	<0.001
Difference in Least Squares Means [4]	-2.64
95% Confidence Interval	-3.90 to -1.38

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in Total Hip Areal BMD

Groups [1]	MK-5442 7.5 mg vs. Alendronate 70 mg

Method [2]	Longitudinal Data Analysis Model
P Value [3]	<0.001
Difference in Least Squares Means [4]	-2.62
95% Confidence Interval	-3.83 to -1.40

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in Total Hip Areal BMD

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	<0.001
Difference in Least Squares Means [4]	-2.12
95% Confidence Interval	-3.22 to -1.02

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in Total Hip Areal BMD

Groups [1]	Placebo vs. MK-5442 5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.376
Difference in Least Square Means [4]	-0.74

95% Confidence Interval	-1.99 to 0.52

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in Total Hip Areal BMD

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.376
Difference in Least Squares Means [4]	-0.71
95% Confidence Interval	-1.93 to 0.50

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in Total Hip Areal BMD

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.699
Difference in Least Squares Means [4]	-0.22
95% Confidence Interval	-1.32 to 0.88

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

6. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Femoral Neck Areal BMD [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Femoral Neck Areal BMD
Measure Description	Areal bone mineral density (BMD) was measured using DXA scanning technology. Scanning is performed with two X-ray beams with different energy levels which are aimed at the participant's bones. When soft tissue absorption is subtracted out, the BMD is determined from the absorption of each beam by bone. BMD = BMC / W, where BMD = bone mineral density in g/cm^2, BMC = bone mineral content in g/cm, and W = width at the scanned line in cm
Time Frame	Baseline and Month 12
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.
Full Analysis Set (FAS): participants who received at least one dose of study treatment, had at least one post-randomization observation, and who had baseline data. The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**Alendronate 70 mg**

Number of Participants Analyzed [units: participants]	**81**	**82**	**79**	**78**	**79**
Least Squares Mean Percent Change From Baseline to Month 12 in Femoral Neck Areal BMD [units: percent change] Least Squares Mean (95% Confidence Interval)	**-1.26 (-2.15 to -0.36)**	**-2.12 (-3.00 to -1.23)**	**-1.37 (-2.29 to -0.44)**	**-1.84 (-2.80 to -0.88)**	**-0.08 (-1.01 to 0.85)**

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in Femoral Neck Areal BMD

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.002
Difference in Least Squares Means [4]	-2.04
95% Confidence Interval	-3.43 to -0.64

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in Femoral Neck Areal BMD

Groups [1]	MK-5442 7.5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.035
Difference in Least Squares Means [4]	-1.29
95% Confidence Interval	-2.48 to -0.09

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	

	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in Femoral Neck Areal BMD

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.009
Difference in Least Squares Means [4]	-1.76
95% Confidence Interval	-3.14 to -0.38

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in Femoral Neck Areal BMD

Groups [1]	Placebo vs. MK-5442 5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.335
Difference in Least Squares Means [4]	-0.86
95% Confidence Interval	-2.26 to 0.54

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in Femoral Neck Areal BMD

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.857
Difference in Least Squares Means [4]	-0.11
95% Confidence Interval	-1.30 to 1.08

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in Femoral Neck Areal BMD

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.542
Difference in Least Squares Means [4]	-0.59
95% Confidence Interval	-1.96 to 0.79

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

7. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Trochanter Areal BMD [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Trochanter Areal BMD

Measure Description	Areal bone mineral density (BMD) was measured using DXA scanning technology. Scanning is performed with two X-ray beams with different energy levels which are aimed at the participant's bones. When soft tissue absorption is subtracted out, the BMD is determined from the absorption of each beam by bone. BMD = BMC / W, where BMD = bone mineral density in g/cm^2, BMC = bone mineral content in g/cm, and W = width at the scanned line in cm
Time Frame	Baseline and Month 12
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.
Full Analysis Set (FAS): participants who received at least one dose of study treatment, had at least one post-randomization observation, and who had baseline data. The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**Alendronate 70 mg**
Number of Participants Analyzed [units: participants]	**81**	**82**	**79**	**78**	**79**
Least Squares Mean Percent Change From Baseline to Month 12 in Trochanter Areal BMD [units: percent change] Least Squares Mean (95% Confidence Interval)	**-0.30 (-1.35 to 0.76)**	**-1.56 (-2.60 to -0.52)**	**-1.50 (-2.59 to -0.41)**	**-1.52 (-2.66 to -0.38)**	**1.68 (0.59 to 2.76)**

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in Trochanter Areal BMD

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	<0.001
Difference in Least Squares Means [4]	-3.24

95% Confidence Interval	-4.91 to -1.57

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in Trochanter Areal BMD

Groups [1]	MK-5442 7.5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	<0.001
Difference in Least Square Means [4]	-3.18
95% Confidence Interval	-4.78 to -1.57

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in Trochanter Areal BMD

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	<0.001
Difference in Least Squares Means [4]	-3.20
95% Confidence Interval	-4.66 to -1.74

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in Trochanter Areal BMD

Groups [1]	Placebo vs. MK-5442 5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.180
Difference in Least Squares Means [4]	-1.27
95% Confidence Interval	-2.93 to 0.40

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in Trochanter Areal BMD

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.180
Difference in Least Squares Means [4]	-1.20
95% Confidence Interval	-2.81 to 0.40

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time

	point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in Trochanter Areal BMD

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.180
Difference in Least Squares Means [4]	-1.22
95% Confidence Interval	-2.68 to 0.23

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

8. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Total Body Areal BMD [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Total Body Areal BMD
Measure Description	Areal bone mineral density (BMD) was measured using DXA scanning technology. Scanning is performed with two X-ray beams with different energy levels which are aimed at the participant's bones. When soft tissue absorption is subtracted out, the BMD is determined from the absorption of each beam by bone. BMD = BMC / W, where BMD = bone mineral density in g/cm^2, BMC = bone mineral content in g/cm, and W = width at the scanned line in cm
Time Frame	Baseline and Month 12
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.
Full Analysis Set (FAS): participants who received at least one dose of study treatment, had at least one post-randomization observation, and who had baseline data. The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	**68**	**75**	**70**	**74**	**72**
Least Squares Mean Percent Change From Baseline to Month 12 in Total Body Areal BMD [units: percent change] Least Squares Mean (95% Confidence Interval)	**-0.17 (-0.83 to 0.49)**	**-0.54 (-1.18 to 0.10)**	**-0.69 (-1.37 to -0.01)**	**-1.10 (-1.77 to -0.44)**	**0.82 (0.15 to 1.48)**

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in Total Body Areal BMD

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.001
Difference in Least Squares Means [4]	-1.36
95% Confidence Interval	-2.18 to -0.54

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in Total Body Areal BMD

[1]	

Groups	MK-5442 7.5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.001
Difference in Least Squares Means [4]	-1.51
95% Confidence Interval	-2.46 to -0.55

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in Total Body Areal BMD

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	<0.001
Difference in Least Squares Means [4]	-1.92
95% Confidence Interval	-2.93 to -0.91

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in Total Body Areal BMD

Groups [1]	Placebo vs. MK-5442 5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.383
[4]	

Difference in Least Squares Means	-0.37
95% Confidence Interval	-1.21 to 0.46

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in Total Body Areal BMD

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.383
Difference in Least Squares Means [4]	-0.52
95% Confidence Interval	-1.49 to 0.45

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in Total Body Areal BMD

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.084
Difference in Least Squares Means [4]	-0.94
95% Confidence Interval	-1.96 to 0.09

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

9. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in 1/3 Distal Forearm Areal BMD [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in 1/3 Distal Forearm Areal BMD
Measure Description	Areal bone mineral density (BMD) was measured using DXA scanning technology. Scanning is performed with two X-ray beams with different energy levels which are aimed at the participant's bones. When soft tissue absorption is subtracted out, the BMD is determined from the absorption of each beam by bone. BMD = BMC / W, where BMD = bone mineral density in g/cm^2, BMC = bone mineral content in g/cm, and W = width at the scanned line in cm
Time Frame	Baseline and Month 12
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.
Full Analysis Set (FAS): participants who received at least one dose of study treatment, had at least one post-randomization observation, and who had baseline data. The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	67	72	65	66	69
Least Squares Mean Percent Change From Baseline to Month 12 in 1/3 Distal Forearm Areal BMD [units: percent change] Least Squares Mean (95% Confidence Interval)	-0.54 (-1.54 to 0.46)	-1.38 (-2.36 to -0.40)	-0.92 (-1.95 to 0.12)	-2.01 (-3.05 to -0.98)	-0.91 (-1.92 to 0.10)

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in 1/3 Distal Forearm Areal BMD

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.680
Difference in Least Squares Means [4]	-0.47
95% Confidence Interval	-1.88 to 0.94

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in 1/3 Distal Forearm Areal BMD

Groups [1]	MK-5442 7.5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.993
Difference in Least Squares Means [4]	-0.01
95% Confidence Interval	-1.30 to 1.28

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time

	point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in 1/3 Distal Forearm Areal BMD

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.230
Difference in Least Squares Means [4]	-1.10
95% Confidence Interval	-2.67 to 0.46

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in 1/3 Distal Forearm Areal BMD

Groups [1]	Placebo vs. MK-5442 5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.333
Difference in Least Squares Means [4]	-0.84
95% Confidence Interval	-2.29 to 0.61

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in 1/3 Distal Forearm Areal BMD

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.577
Difference in Least Squares Means [4]	-0.37
95% Confidence Interval	-1.69 to 0.94

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in 1/3 Distal Forearm Areal BMD

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.078
Difference in Least Squares Means [4]	-1.47
95% Confidence Interval	-3.07 to 0.12

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

10. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD (vBMD) of the Lumbar Spine [Time Frame: Baseline and Month 12]

Measure Type	Secondary

Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD (vBMD) of the Lumbar Spine
Measure Description	vBMD was measured using quantitative computed tomography (QCT) in order to assess bone strength. Quantitative computed tomography is a three-dimensional non-projectional technique that quantifies trabecular and cortical BMD in the lumbar spine and hip as a true volumetric mineral density in g/cm^3.
Time Frame	Baseline and Month 12
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.
Full Analysis Set (FAS), QCT Subset: QCT was performed on a subset of the FAS (participants who received at least one dose of study treatment, had at least one post-randomization observation, and who had baseline data). The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**Alendronate 70 mg**
Number of Participants Analyzed [units: participants]	**45**	**58**	**49**	**49**	**43**
Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD (vBMD) of the Lumbar Spine [units: percent change] Least Squares Mean (95% Confidence Interval)	**0.18 (-1.22 to 1.57)**	**-0.25 (-1.55 to 1.05)**	**0.08 (-1.29 to 1.44)**	**0.16 (-1.28 to 1.61)**	**1.74 (0.21 to 3.26)**

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD (vBMD) of the Lumbar Spine

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.094

Difference in Least Squares Means [4]	-1.99
95% Confidence Interval	-4.22 to 0.25

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD (vBMD) of the Lumbar Spine

Groups [1]	MK-5442 7.5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.157
Difference in Least Squares Means [4]	-1.66
95% Confidence Interval	-3.82 to 0.50

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD (vBMD) of the Lumbar Spine

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.157
Difference in Least Squares Means [4]	-1.57
95% Confidence Interval	-3.53 to 0.38

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD (vBMD) of the Lumbar Spine

Groups [1]	Placebo vs. MK-5442 5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.937
Difference in Least Squares Means [4]	-0.43
95% Confidence Interval	-2.61 to 1.76

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD (vBMD) of the Lumbar Spine

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.992
Difference in Least Squares Means [4]	-0.10
95% Confidence Interval	-2.21 to 2.01

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD (vBMD) of the Lumbar Spine

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.992
Difference in Least Squares Means [4]	-0.01
95% Confidence Interval	-1.93 to 1.90

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

11. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD of the Hip [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD of the Hip
Measure Description	vBMD was measured using QCT in order to assess bone strength. QCT is a three-dimensional non-projectional technique that quantifies trabecular and cortical BMD in the lumbar spine and hip as a true volumetric mineral density in g/cm^3.
Time Frame	Baseline and Month 12
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.

Full Analysis Set (FAS), QCT Subset: QCT was performed on a subset of the FAS (participants who received at least one dose of study treatment, had at least one post-randomization observation, and who had baseline data).

The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	**46**	**57**	**48**	**48**	**45**
Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD of the Hip [units: percent change] Least Squares Mean (95% Confidence Interval)	**-0.02 (-1.41 to 1.36)**	**0.76 (-0.53 to 2.05)**	**0.81 (-0.57 to 2.18)**	**0.27 (-1.16 to 1.71)**	**1.23 (-0.23 to 2.70)**

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD of the Hip

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.824
Difference in Least Squares Means [4]	-0.47
95% Confidence Interval	-2.50 to 1.56

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:

	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD of the Hip

Groups [1]	MK-5442 7.5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.824
Difference in Least Squares Means [4]	-0.42
95% Confidence Interval	-2.28 to 1.43

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD of the Hip

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.624
Difference in Least Squares Means [4]	-0.96
95% Confidence Interval	-3.23 to 1.31

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD of the Hip

Groups [1]	Placebo vs. MK-5442 5 mg

Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.700
Difference in Least Squares Means [4]	0.78
95% Confidence Interval	-1.25 to 2.82

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD of the Hip

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.700
Difference in Least Squares Means [4]	0.83
95% Confidence Interval	-1.39 to 3.06

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in Trabecular Volumetric BMD of the Hip

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.759
Difference in Least Squares Means [4]	0.30

95% Confidence Interval	-1.60 to 2.19

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

12. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Lumbar Spine [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Lumbar Spine
Measure Description	vBMD was measured using QCT in order to assess bone strength. QCT is a three-dimensional non-projectional technique that quantifies trabecular and cortical BMD in the lumbar spine and hip as a true volumetric mineral density in g/cm^3.
Time Frame	Baseline and Month 12
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.
Full Analysis Set (FAS), QCT Subset: QCT was performed on a subset of the FAS (participants who received at least one dose of study treatment, had at least one post-randomization observation, and who had baseline data). The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	45	58	49	49	43
Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Lumbar Spine [units: percent change] Least Squares Mean (95% Confidence Interval)	-0.67 (-15.01 to 13.66)	-3.41 (-16.35 to 9.52)	14.66 (0.91 to 28.41)	-0.34 (-14.49 to 13.82)	12.80 (-2.31 to 27.92)

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Lumbar Spine

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.227
Difference in Least Squares Means [4]	-16.22
95% Confidence Interval	-39.15 to 6.72

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Lumbar Spine

Groups [1]	MK-5442 7.5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.853
Difference in Least Squares Means [4]	1.85
95% Confidence Interval	-17.90 to 21.61

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Lumbar Spine

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.327
Difference in Least Squares Means [4]	-13.14
95% Confidence Interval	-35.67 to 9.39

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Lumbar Spine

Groups [1]	Placebo vs. MK-5442 5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.940
Difference in Least Squares Means [4]	-2.74
95% Confidence Interval	-23.91 to 18.43

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:

	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Lumbar Spine

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.273
Difference in Least Squares Means [4]	15.33
95% Confidence Interval	-7.86 to 38.52

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Lumbar Spine

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.973
Difference in Least Squares Means [4]	0.33
95% Confidence Interval	-19.23 to 19.90

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

13. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Hip [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Hip
Measure Description	vBMD was measured using QCT in order to assess bone strength. QCT is a three-dimensional non-projectional technique that quantifies trabecular and cortical BMD in the lumbar spine and hip as a true volumetric mineral density in g/cm^3.
Time Frame	Baseline and Month 12
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.
Full Analysis Set (FAS), QCT Subset: QCT was performed on a subset of the FAS (participants who received at least one dose of study treatment, had at least one post-randomization observation, and who had baseline data). The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcomes analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**Alendronate 70 mg**
Number of Participants Analyzed [units: participants]	**46**	**57**	**48**	**48**	**45**
Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Hip [units: percent change] Least Squares Mean (95% Confidence Interval)	**0.10 (-0.67 to 0.86)**	**-0.49 (-1.19 to 0.22)**	**-0.15 (-0.90 to 0.60)**	**-0.16 (-0.94 to 0.62)**	**0.99 (0.19 to 1.78)**

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Hip

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.010
[4]	-1.48

Difference in Least Squares Means	
95% Confidence Interval	-2.66 to -0.29

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Hip

Groups [1]	MK-5442 7.5 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.053
Difference in Least Squares Means [4]	-1.14
95% Confidence Interval	-2.29 to 0.01

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Hip

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.053
Difference in Least Squares Means [4]	-1.15
95% Confidence Interval	-2.19 to -0.11

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Hip

Groups [1]	Placebo vs. MK-5442 5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.509
Difference in Least Squares Means [4]	-0.58
95% Confidence Interval	-1.77 to 0.60

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Hip

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.843
Difference in Least Squares Means [4]	-0.25
95% Confidence Interval	-1.27 to 0.77

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:

	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in Cortical Volumetric BMD of the Hip

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.843
Difference in Least Squares Means [4]	-0.26
95% Confidence Interval	-1.43 to 0.92

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

14. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Urinary-N Telopeptides of Type 1 Collagen (u-NTx) [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Urinary-N Telopeptides of Type 1 Collagen (u-NTx)
Measure Description	Urinary, type I collagen, crosslinked N-telopeptide (uNTx) is a biomarker used to measure the rate of bone turnover found in urine. uNTx was expressed in units of nanomoles (nM) per bone collagen equivalents (BCE) per millimoles of creatinine (Cr) or nM/BCE/mM Cr
Time Frame	Baseline and Month 12
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.
Per Protocol Population: defined as the subset of the APaT population that excluded participants based on critical protocol violations. The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	**68**	**71**	**68**	**73**	**67**
Least Squares Mean Percent Change From Baseline to Month 12 in Urinary-N Telopeptides of Type 1 Collagen (u-NTx) [units: percent change] Least Squares Mean (95% Confidence Interval)	**63.64 (47.71 to 81.29)**	**86.51 (68.86 to 106.01)**	**83.32 (64.49 to 102.08)**	**107.44 (86.65 to 130.54)**	**0.18 (-9.45 to 10.83)**

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in Urinary-N Telopeptides of Type 1 Collagen (u-NTx)

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	86.33
95% Confidence Interval	64.87 to 108.29

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in Urinary-N Telopeptides of Type 1 Collagen (u-NTx)

Groups [1]	MK-5442 7.5 mg vs. Alendronate 70 mg

Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	82.14
95% Confidence Interval	63.00 to 101.66

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in Urinary-N Telopeptides of Type 1 Collagen (u-NTx)

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	107.26
95% Confidence Interval	82.03 to 133.23

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in Urinary-N Telopeptides of Type 1 Collagen (u-NTx)

Groups [1]	Placebo vs. MK-5442 5 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.104
Difference in Least Squares Means [4]	22.87

95% Confidence Interval	-3.80 to 49.68

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in Urinary-N Telopeptides of Type 1 Collagen (u-NTx)

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.123
Difference in Least Squares Means [4]	18.68
95% Confidence Interval	-5.11 to 42.56

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in Urinary-N Telopeptides of Type 1 Collagen (u-NTx)

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.003
Difference in Least Squares Means [4]	43.80
95% Confidence Interval	12.85 to 75.06

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

15. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Serum C-Terminal Propeptide of Type 1 Collagen (s-CTx) [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Serum C-Terminal Propeptide of Type 1 Collagen (s-CTx)
Measure Description	C-Terminal Telopeptide Collagen I is used as a serum-marker of bone resorption in the assessment of osteoporosis and in measured in units of nanograms (n)/milliliter (ml).
Time Frame	Baseline and Month 12
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.
Per Protocol Population: defined as the subset of the APaT population that excluded participants based on critical protocol violations. The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**Alendronate 70 mg**
Number of Participants Analyzed [units: participants]	**70**	**73**	**69**	**72**	**71**
Least Squares Mean Percent Change From					

Baseline to Month 12 in Serum C-Terminal Propeptide of Type 1 Collagen (s-CTx) [units: percent change] Least Squares Mean (95% Confidence Interval)	**165.80 (131.23 to 205.54)**	**214.09 (173.92 to 260.15)**	**227.07 (184.11 to 276.53)**	**251.08 (204.31 to 305.04)**	**26.78 (10.58 to 45.36)**

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum C-Terminal Propeptide of Type 1 Collagen (s-CTx)

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	187.31
95% Confidence Interval	154.44 to 221.25

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum C-Terminal Propeptide of Type 1 Collagen (s-CTx)

Groups [1]	MK-5442 7.5 mg vs. Alendronate 70 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	200.29
95% Confidence Interval	161.21 to 240.91

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:

	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum C-Terminal Propeptide of Type 1 Collagen (s-CTx)

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	224.30
95% Confidence Interval	180.19 to 270.39

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum C-Terminal Propeptide of Type 1 Collagen (s-CTx)

Groups [1]	Placebo vs. MK-5442 5 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.034
Difference in Least Squares Means [4]	48.29
95% Confidence Interval	3.75 to 93.11

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum C-Terminal Propeptide of Type 1 Collagen (s-

CTx)

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.019
Difference in Least Squares Means [4]	61.27
95% Confidence Interval	8.80 to 114.22

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum C-Terminal Propeptide of Type 1 Collagen (s-CTx)

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.002
Difference in Least Squares Means [4]	85.28
95% Confidence Interval	26.70 to 144.63

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

16. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Serum N-Terminal Propeptide (s-P1NP) [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Serum N-Terminal Propeptide (s-P1NP)
Measure Description	s-P1NP is a sensitive marker of bone formation rate in the assessment of osteoporosis and is measured in units of ng/ml.
Time Frame	Baseline and Month 12
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.
Per Protocol Population: defined as the subset of the APaT population that excluded participants based on critical protocol violations. The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**Alendronate 70 mg**
Number of Participants Analyzed [units: participants]	**70**	**73**	**69**	**73**	**71**
Least Squares Mean Percent Change From Baseline to Month 12 in Serum N-Terminal Propeptide (s-P1NP) [units: percent change] Least Squares Mean (95% Confidence Interval)	**68.61 (51.82 to 87.27)**	**127.18 (105.07 to 151.68)**	**125.69 (102.92 to 151.01)**	**163.96 (136.79 to 194.24)**	**-5.85 (-14.99 to 4.28)**

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum N-Terminal Propeptide (s-P1NP)

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	133.03
95% Confidence Interval	110.01 to 156.75

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum N-Terminal Propeptide (s-P1NP)

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.001
Difference in Least Squares Means [4]	133.03
95% Confidence Interval	110.01 to 156.75

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum N-Terminal Propeptide (s-P1NP)

Groups [1]	MK-5442 7.5 mg vs. Alendronate 70 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	131.53
95% Confidence Interval	110.70 to 152.94

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum N-Terminal Propeptide (s-P1NP)

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	169.80
95% Confidence Interval	141.59 to 199.11

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum N-Terminal Propeptide (s-P1NP)

Groups [1]	Placebo vs. MK-5442 5 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	58.57
95% Confidence Interval	29.42 to 88.04

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:

	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum N-Terminal Propeptide (s-P1NP)

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	57.07
95% Confidence Interval	30.76 to 83.64

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 7 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum N-Terminal Propeptide (s-P1NP)

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	95.34
95% Confidence Interval	60.40 to 130.91

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

17. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP) [Time

Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)
Measure Description	Bone Specific Alkaline Phosphatase is a biomarker of bone formation and is measured in units of µg/L.
Time Frame	Baseline and Month 12
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.
Per Protocol Population: defined as the subset of the APaT population that excluded participants based on critical protocol violations. The MK-5442 15-mg treatment arm was discontinued as a result of Amendment 1 and thus no outcome analyses were performed.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.
MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**Alendronate 70 mg**
Number of Participants Analyzed [units: participants]	**69**	**72**	**68**	**73**	**71**
Least Squares Mean Percent Change From Baseline to Month 12 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP) [units: percent change] Least Squares Mean (95% Confidence Interval)	**29.51 (20.23 to 39.51)**	**50.04 (39.60 to 61.25)**	**49.98 (39.08 to 61.73)**	**51.64 (40.42 to 63.76)**	**-3.83 (-10.41 to 3.24)**

Statistical Analysis 1 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)

Groups [1]	MK-5442 5 mg vs. Alendronate 70 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	53.86

95% Confidence Interval	39.31 to 68.60

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)

Groups [1]	MK-5442 7.5 mg vs. Alendronate 70 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	53.81
95% Confidence Interval	41.37 to 66.38

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)

Groups [1]	MK-5442 10 mg vs. Alendronate 70 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	<0.001
Difference in Least Squares Means [4]	55.47
95% Confidence Interval	41.19 to 69.94

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)

Groups [1]	Placebo vs. MK-5442 5 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.009
Difference in Least Squares Means [4]	20.53
95% Confidence Interval	5.96 to 35.03

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)

Groups [1]	Placebo vs. MK-5442 7.5 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.009
Difference in Least Mean Squares [4]	20.47
95% Confidence Interval	5.96 to 35.03

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time

	point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 6 for Least Squares Mean Percent Change From Baseline to Month 12 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)

Groups [1]	Placebo vs. MK-5442 10 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.009
Difference in Least Squares Means [4]	22.13
95% Confidence Interval	4.47 to 39.89

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[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:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 12, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

18. Secondary: Least Squares Mean Percent Change From Baseline to Month 12 in Serum Osteocalcin [Time Frame: Baseline and Month 12]

Measure Type	Secondary
Measure Title	Least Squares Mean Percent Change From Baseline to Month 12 in Serum Osteocalcin
Measure Description	Serum osteocalcin is a biomarker of bone formation and is measured using units of nanograms (ng) / milliliter (mL).
Time Frame	Baseline and Month 12
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.
Analysis of osteocalcin was not conducted when it was determined that the efficacy of MK-5442 was not significantly different than placebo.

Reporting Groups

	Description
Placebo	Participants received oral matching placebo for MK-5442 or alendronate, based on their randomization to active drug or comparator arm.

MK-5442 5 mg	Participants were randomized to receive oral, once-daily MK-5442 5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 7.5 mg	Participants were randomized to receive oral, once-daily MK-5442 7.5 mg and once-weekly matching placebo to alendronate for 12 months.
MK-5442 10 mg	Participants were randomized to receive oral, once-daily MK-5442 10 mg and once-weekly matching placebo to alendronate for 12 months.
Alendronate 70 mg	Participants were randomized to receive oral, once-weekly alendronate 70 mg plus once-daily matching placebo to MK-5442 for 12 months.

Measured Values

	Placebo	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**	**0**
Least Squares Mean Percent Change From Baseline to Month 12 in Serum Osteocalcin					

No statistical analysis provided for Least Squares Mean Percent Change From Baseline to Month 12 in Serum Osteocalcin

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	All Participants as Treated (APaT); all randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Placebo	Participants received either matching placebo to alendronate (administered orally, once-weekly) or matching placebo to MK-5442 (administered orally, once-daily) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
MK-5442 5 mg	Participants received 5 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
MK-5442 7.5 mg	Participants received 7.5 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
MK-5442 10 mg	Participants received 10 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
MK-5442 15 mg	Participants received 15 mg of MK-5442 (orally, once-daily) plus matching placebo to alendronate (administered orally, once-weekly) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.
Alendronate 70 mg	Participants received 70 mg alendronate (orally, once-weekly) plus matching placebo to MK-5442 (administered orally, once-daily) for 12 months. Participants also received supplemental vitamin D3 and calcium (as needed) during treatment.

Serious Adverse Events

	Placebo	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Alendronate 70 mg
Total, serious adverse events						
# participants affected / at risk	6/88 (6.82%)	5/87 (5.75%)	4/88 (4.55%)	6/87 (6.90%)	4/88 (4.55%)	1/88 (1.14%)
Cardiac disorders						
Angina Pectoris † 1						
# participants affected / at risk	0/88 (0.00%)	1/87 (1.15%)	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	1	0	0	0	0
Coronary Heart Disease † 1						
# participants affected / at risk	0/88 (0.00%)	1/87 (1.15%)	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	1	0	0	0	0
Hypertensive Heart Disease † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/87 (0.00%)	1/88 (1.14%)	0/88 (0.00%)
# events	0	0	0	0	1	0
Tako-Tsubo Cardiomyopathy † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	1/87 (1.15%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	0	0	1	0	0
Gastrointestinal disorders						
Gastroenteritis Eosinophilic † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/87 (0.00%)	1/88 (1.14%)	0/88 (0.00%)
# events	0	0	0	0	1	0
General disorders						
Hernia † 1						
# participants affected / at risk	0/88 (0.00%)	1/87 (1.15%)	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	1	0	0	0	0
Hepatobiliary disorders						
Biliary Fistula † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/87 (0.00%)	1/88 (1.14%)	0/88 (0.00%)
# events	0	0	0	0	1	0
Cholelithiasis † 1						
						0/88 (0.00%)

# participants affected / at risk	1/88 (1.14%)	0/87 (0.00%)	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	
# events	1	0	0	0	0	0
Infections and infestations						
Acute Appendicitis † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	1/88 (1.14%)	0/87 (0.00%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	0	1	0	0	0
Campylobacter Gastroenteritis † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	1/87 (1.15%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	0	0	1	0	0
Urinary Tract Infection † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/87 (0.00%)	1/88 (1.14%)	0/88 (0.00%)
# events	0	0	0	0	1	0
Injury, poisoning and procedural complications						
Postoperative Pain † 1						
# participants affected / at risk	1/88 (1.14%)	0/87 (0.00%)	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/88 (0.00%)
# events	1	0	0	0	0	0
Postoperative Wound Complication † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/87 (0.00%)	1/88 (1.14%)	0/88 (0.00%)
# events	0	0	0	0	1	0
Radius Fracture † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	1/88 (1.14%)	1/87 (1.15%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	0	1	1	0	0
Musculoskeletal and connective tissue disorders						
Foot Osteoarthritis † 1						
# participants affected / at risk	1/88 (1.14%)	0/87 (0.00%)	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/88 (0.00%)
# events	1	0	0	0	0	0
Low Back Pain † 1						
# participants affected / at risk	0/88 (0.00%)	1/87 (1.15%)	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	1	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Basal Cell Carcinoma † 1						
						1/88 (1.14%)

# participants affected / at risk	1/88 (1.14%)	0/87 (0.00%)	1/88 (1.14%)	0/87 (0.00%)	0/88 (0.00%)	
# events	2	0	1	0	0	1
Breast Cancer † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/87 (0.00%)	1/88 (1.14%)	0/88 (0.00%)
# events	0	0	0	0	1	0
Cancer of the Head of the Pancreas † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	1/88 (1.14%)	0/87 (0.00%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	0	1	0	0	0
Latigo Maligna Stage Unspecified † 1						
# participants affected / at risk	0/88 (0.00%)	1/87 (1.15%)	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	1	0	0	0	0
Lung Neoplasm Malignant † 1						
# participants affected / at risk	1/88 (1.14%)	0/87 (0.00%)	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/88 (0.00%)
# events	1	0	0	0	0	0
Nervous system disorders						
Carotid Artery Stenosis † 1						
# participants affected / at risk	1/88 (1.14%)	0/87 (0.00%)	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/88 (0.00%)
# events	1	0	0	0	0	0
Cerebral Thrombosis † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	1/87 (1.15%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	0	0	1	0	0
Dizziness † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	1/87 (1.15%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	0	0	1	0	0
Migraine with Aura † 1						
# participants affected / at risk	1/88 (1.14%)	0/87 (0.00%)	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	0/88 (0.00%)
# events	1	0	0	0	0	0
Anxiety Aggravated † 1						
# participants affected / at risk	0/88 (0.00%)	0/87 (0.00%)	0/88 (0.00%)	1/87 (1.15%)	0/88 (0.00%)	0/88 (0.00%)
# events	0	0	0	1	0	0
Respiratory, thoracic and mediastinal disorders						
Pulmonary Thromboembolism † 1						

# participants affected / at risk	**0/88 (0.00%)**	**0/87 (0.00%)**	**0/88 (0.00%)**	**0/87 (0.00%)**	**1/88 (1.14%)**	**0/88 (0.00%)**
# events	**0**	**0**	**0**	**0**	**1**	**0**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	All Participants as Treated (APaT); all randomized participants who received at least one dose of study treatment.

Frequency Threshold

Threshold above which other adverse events are reported	5.0%

Reporting Groups

	Description
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Other Adverse Events

	Placebo	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**MK-5442 15 mg**	**Alendronate 70 mg**
Total, other (not including serious) adverse events						
# participants affected / at risk	**18/88 (20.45%)**	**18/87 (20.69%)**	**26/88 (29.55%)**	**32/87 (36.78%)**	**28/88 (31.82%)**	**10/84 (11.90%)**
Gastrointestinal disorders						
Constipation † 1						

# participants affected / at risk	3/88 (3.41%)	1/87 (1.15%)	5/88 (5.68%)	3/87 (3.45%)	1/88 (1.14%)	2/84 (2.38%)
# events	3	1	5	4	1	2
Metabolism and nutrition disorders						
Hypercalcaemia † 1						
# participants affected / at risk	0/88 (0.00%)	1/87 (1.15%)	8/88 (9.09%)	10/87 (11.49%)	23/88 (26.14%)	0/84 (0.00%)
# events	0	1	8	12	23	0
Musculoskeletal and connective tissue disorders						
Back Pain † 1						
# participants affected / at risk	3/88 (3.41%)	2/87 (2.30%)	1/88 (1.14%)	8/87 (9.20%)	2/88 (2.27%)	1/84 (1.19%)
# events	3	2	1	8	2	1
Knee Pain † 1						
# participants affected / at risk	1/88 (1.14%)	0/87 (0.00%)	6/88 (6.82%)	3/87 (3.45%)	0/88 (0.00%)	1/84 (1.19%)
# events	1	0	6	3	0	1
Nervous system disorders						
Headache † 1						
# participants affected / at risk	2/88 (2.27%)	1/87 (1.15%)	7/88 (7.95%)	1/87 (1.15%)	2/88 (2.27%)	3/84 (3.57%)
# events	2	1	7	1	2	3
Respiratory, thoracic and mediastinal disorders						
Upper Respiratory Tract Infection † 1						
# participants affected / at risk	6/88 (6.82%)	5/87 (5.75%)	1/88 (1.14%)	3/87 (3.45%)	1/88 (1.14%)	0/84 (0.00%)
# events	7	5	1	3	1	0
Urinary Tract Infection † 1						
# participants affected / at risk	5/88 (5.68%)	8/87 (9.20%)	6/88 (6.82%)	6/87 (6.90%)	2/88 (2.27%)	5/84 (5.95%)
# events	9	10	9	8	2	6

† 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

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:

- [x] 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.

Results Point of Contact:

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Publications of Results:

Cosman F, Gilchrist N, McClung M, Foldes J, de Villiers T, Santora A, Leung A, Samanta S, Heyden N, McGinnis JP 2nd, Rosenberg E, Denker AE. A phase 2 study of MK-5442, a calcium-sensing receptor antagonist, in postmenopausal women with osteoporosis after long-term use of oral bisphosphonates. Osteoporos Int. 2016 Jan;27(1):377-86. doi: 10.1007/s00198-015-3392-7. Epub 2015 Nov 10.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00996801 History of Changes
Other Study ID Numbers:	5442-012 2009-014729-18 (EudraCT Number) CTRI/2010/091/000258 (Registry Identifier: CTRI)
Study First Received:	October 15, 2009
Results First Received:	August 31, 2012
Last Updated:	January 21, 2016
Health Authority:	United States: Food and Drug Administration

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