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Trial record **1 of 1** for: CZOL446HDE31

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Safety/Efficacy of Zoledronic Acid and Alendronate on Bone Metabolism in Postmenopausal Women With Osteoporosis (ROSE)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00404820

First received: November 28, 2006
Last updated: June 6, 2011
Last verified: June 2011
History of Changes

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Results First Received: January 5, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Osteoporosis
Interventions:	Drug: Zoledronic acid 5 mg solution Drug: Alendronate 70 mg tablets Drug: Calcium/Vitamin D

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
The study was conducted in Germany; first patient enrolled October 2006 and completed December 2008.

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
Zoledronic Acid 5 mg	Patients received zoledronic acid 5 mg in 100 ml solution in a 15 minute intravenous (iv) infusion once per year. The peripheral iv infusion was preceded by and followed by a 10 ml normal saline flush of the intravenous line. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.
Alendronate 70 mg	Patients received an alendronate 70 mg tablet once weekly with 200 ml of tap water in the morning on an empty stomach at least 30 minutes before the first meal. Patients were to remain in an upright position for 30 minutes after swallowing the tablet. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.

Participant Flow: Overall Study

	Zoledronic Acid 5 mg	Alendronate 70 mg
STARTED	408	196
Started Treatment	408	194 [1]
COMPLETED	389	172
NOT COMPLETED	19	24
Adverse Event	4	16
Withdrawal by Subject	5	3
Lost to Follow-up	7	3
Administrative problems	2	0
Death	1	0
Unknown	0	2

[1] The reason why 2 patients did not start treatment is unavailable.

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
Zoledronic Acid 5 mg	Patients received zoledronic acid 5 mg in 100 ml solution in a 15 minute intravenous (iv) infusion once per year. The peripheral iv infusion was preceded by and followed by a 10 ml normal saline flush of the intravenous line. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.
Alendronate 70 mg	Patients received an alendronate 70 mg tablet once weekly with 200 ml of tap water in the morning on an empty stomach at least 30 minutes before the first meal. Patients were to remain in an upright position for 30 minutes after swallowing the tablet. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.
Total	Total of all reporting groups

Baseline Measures

	Zoledronic Acid 5 mg	Alendronate 70 mg	Total
Number of Participants [units: participants]	408	194	602
Age [units: years] Mean (Standard Deviation)	67.6 (8.1)	68.2 (7.9)	67.8 (8.0)
Gender [units: participants]			
Female	408	194	602
Male	0	0	0

Outcome Measures

Hide All Outcome Measures

1. Primary: Change of Cross-linked N-telopeptide of Type I Collagen (NTx) Level Assessed as Standardized Area Under the Curve From Screening to Month 12 in the Intent-to-Treat Population [Time Frame: Screening to end of study (Month 12)]

Measure Type	Primary
Measure Title	Change of Cross-linked N-telopeptide of Type I Collagen (NTx) Level Assessed as Standardized Area Under the Curve From Screening to Month 12 in the Intent-to-Treat Population
Measure Description	The level of bone activity as measured by NTx over the course of 12 months was assessed using the standardized area under the curve. Blood samples were collected after an overnight fast of at least 8 hours between 7:00 and 11:00 AM at Screening and Months 1.5, 3, 6, 9, and 12 months after baseline. Serum was analyzed at a central lab using commercially available ELISA kits. Standardized AUC was calculated by the AUC divided by the number of days the patient participated in the study.
Time Frame	Screening to end of study (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.
Intent-to-treat sample (ITT) population: All patients who received at least 1 dose of study medication and who had at least 1 post-baseline determination of cross-linked N-telopeptide of type I collagen (NTx) level.

Reporting Groups

	Description
Zoledronic Acid 5 mg	Patients received zoledronic acid 5 mg in 100 ml solution in a 15 minute intravenous (iv) infusion once per year. The peripheral iv infusion was preceded by and followed by a 10 ml normal saline flush of the intravenous line. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.
Alendronate 70 mg	Patients received an alendronate 70 mg tablet once weekly with 200 ml of tap water in the morning on an empty stomach at least 30 minutes before the first meal. Patients were to remain in an upright position for 30 minutes after swallowing the tablet. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.

Measured Values

	Zoledronic Acid 5 mg	**Alendronate 70 mg**
Number of Participants Analyzed [units: participants]	**408**	**191**
Change of Cross-linked N-telopeptide of Type I Collagen (NTx) Level Assessed as Standardized Area Under the Curve From Screening to Month 12 in the Intent-to-Treat Population [units: ng/ml] Mean (Standard Deviation)	**0.282 (0.195)**	**0.270 (0.266)**

No statistical analysis provided for Change of Cross-linked N-telopeptide of Type I Collagen (NTx) Level Assessed as Standardized Area Under the Curve From Screening to Month 12 in the Intent-to-Treat Population

2. Primary: Change of Cross-linked N-telopeptide of Type I Collagen (NTx) Level Assessed as Standardized Area Under the Curve From Screening to Month 12 in the Per Protocol Population [Time Frame: Screening to end of study (Month 12)]

Measure Type	Primary

Measure Title	Change of Cross-linked N-telopeptide of Type I Collagen (NTx) Level Assessed as Standardized Area Under the Curve From Screening to Month 12 in the Per Protocol Population
Measure Description	The level of bone activity as measured by NTx over the course of 12 months was assessed using the standardized area under the curve. Blood samples were collected after an overnight fast of at least 8 hours between 7:00 and 11:00 AM at Screening and Months 1.5, 3, 6, 9, and 12 months after baseline. Serum was analyzed at a central lab using commercially available ELISA kits. Standardized AUC was calculated by the AUC divided by the number of days the patient participated in the study.
Time Frame	Screening to end of study (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: All intent-to-treat patients who did not show major deviations from the protocol procedures that may have had an impact on the study outcome.

Reporting Groups

	Description
Zoledronic Acid 5 mg	Patients received zoledronic acid 5 mg in 100 ml solution in a 15 minute intravenous (iv) infusion once per year. The peripheral iv infusion was preceded by and followed by a 10 ml normal saline flush of the intravenous line. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.
Alendronate 70 mg	Patients received an alendronate 70 mg tablet once weekly with 200 ml of tap water in the morning on an empty stomach at least 30 minutes before the first meal. Patients were to remain in an upright position for 30 minutes after swallowing the tablet. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.

Measured Values

	Zoledronic Acid 5 mg	**Alendronate 70 mg**
Number of Participants Analyzed [units: participants]	**349**	**146**
Change of Cross-linked N-telopeptide of Type I Collagen (NTx) Level Assessed as Standardized Area Under the Curve From Screening to Month 12 in the Per Protocol Population [units: ng/ml] Mean (Standard Deviation)	**0.293 (0.199)**	**0.294 (0.175)**

No statistical analysis provided for Change of Cross-linked N-telopeptide of Type I Collagen (NTx) Level Assessed as Standardized Area Under the Curve From Screening to Month 12 in the Per Protocol Population

3. Secondary: Change of Procollagen Type I Nitrogenous Propeptide (P1NP) Level Assessed as Standardized Area Under the Curve From Screening to Month 12 [Time Frame: Screening to end of study (Month 12)]

Measure Type	Secondary
Measure Title	Change of Procollagen Type I Nitrogenous Propeptide (P1NP) Level Assessed as Standardized Area Under the Curve From Screening to Month 12
Measure Description	The level of bone activity as measured by P1NP over the course of 12 months was assessed using the standardized area under the curve. Blood samples were collected after an overnight fast of at least 8 hours between 7:00 and 11:00 AM at Screening and Months 1.5, 3, 6, 9, and 12 months after baseline. Serum was analyzed at a central lab using commercially available ELISA kits. Standardized AUC was calculated by the AUC divided by the number of days the patient participated in the study.
Time Frame	Screening to end of study (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.
Intent-to-treat sample (ITT) population: All patients who received at least 1 dose of study medication and who had at least 1 post-baseline determination of cross-linked N-telopeptide of type I collagen (NTx) level.

Reporting Groups

	Description
Zoledronic Acid 5 mg	Patients received zoledronic acid 5 mg in 100 ml solution in a 15 minute intravenous (iv) infusion once per year. The peripheral iv infusion was preceded by and followed by a 10 ml normal saline flush of the intravenous line. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.
Alendronate 70 mg	Patients received an alendronate 70 mg tablet once weekly with 200 ml of tap water in the morning on an empty stomach at least 30 minutes before the first meal. Patients were to remain in an upright position for 30 minutes after swallowing the tablet. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.

Measured Values

	Zoledronic Acid 5 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	**408**	**191**
Change of Procollagen Type I Nitrogenous Propeptide (P1NP) Level Assessed as Standardized Area Under the Curve From Screening to Month 12 [units: ng/ml] Mean (Standard Deviation)	**28.2 (23.0)**	**25.5 (17.6)**

No statistical analysis provided for Change of Procollagen Type I Nitrogenous Propeptide (P1NP) Level Assessed as Standardized Area Under the Curve From Screening to Month 12

4. Secondary: Change in the Qualeffo-41 Quality of Life (QoL) Questionnaire Score From Baseline to Month 12 [Time Frame: Baseline to end of study (Month 12)]

Measure Type	Secondary
Measure Title	Change in the Qualeffo-41 Quality of Life (QoL) Questionnaire Score From Baseline to Month 12
Measure Description	The Qualeffo-41 QoL questionnaire was completed by the patient at Baseline and at Month 12. The questionnaire includes 41 questions covering 7 domains (pain, physical function and activities of daily living, physical function and jobs around the house, physical function and mobility, leisure and social activities, general health perception, mental function). Scores on each question range from 1 to 3, 4, or 5. The total score summed over all questions ranges from 41-205 points; the lower the score the higher the quality of life. A negative change score indicates improvement.
Time Frame	Baseline to end of study (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.
Intent-to-treat sample (ITT) population: All patients who received at least 1 dose of study medication and who had at least 1 post-baseline determination of cross-linked N-telopeptide of type I collagen (NTx) level.

Reporting Groups

	Description
Zoledronic Acid 5 mg	Patients received zoledronic acid 5 mg in 100 ml solution in a 15 minute intravenous (iv) infusion once per year. The peripheral iv infusion was preceded by and followed by a 10 ml normal saline flush of the intravenous line. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.
Alendronate 70 mg	Patients received an alendronate 70 mg tablet once weekly with 200 ml of tap water in the morning on an empty stomach at least 30 minutes before the first meal. Patients were to remain in an upright position for 30 minutes after swallowing the tablet. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.

Measured Values

	Zoledronic Acid 5 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	**408**	**191**
Change in the Qualeffo-41 Quality of Life (QoL) Questionnaire Score From Baseline to Month 12 [units: Units on a scale] Mean (Standard Deviation)	**-1.2 (8.8)**	**-0.6 (9.0)**

No statistical analysis provided for Change in the Qualeffo-41 Quality of Life (QoL) Questionnaire Score From Baseline to Month 12

5. Secondary: Number of Patients With a Clinical Fracture From Baseline to Month 12 [Time Frame: Baseline to end of study (Month 12)]

Measure Type	Secondary
Measure Title	Number of Patients With a Clinical Fracture From Baseline to Month 12
Measure Description	A diagnosis of clinical fracture was based on physical examination findings, ie, swelling, tenderness, limited movement, pain.
Time Frame	Baseline to end of study (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.
Intent-to-treat sample (ITT) population: All patients who received at least 1 dose of study medication and who had at least 1 post-baseline determination of cross-linked N-telopeptide of type I collagen (NTx) level.

Reporting Groups

	Description
Zoledronic Acid 5 mg	Patients received zoledronic acid 5 mg in 100 ml solution in a 15 minute intravenous (iv) infusion once per year. The peripheral iv infusion was preceded by and followed by a 10 ml normal saline flush of the intravenous line. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.
Alendronate 70 mg	Patients received an alendronate 70 mg tablet once weekly with 200 ml of tap water in the morning on an empty stomach at least 30 minutes before the first meal. Patients were to remain in an upright position for 30 minutes after swallowing the tablet. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.

Measured Values

	Zoledronic Acid 5 mg	Alendronate 70 mg
Number of Participants Analyzed	**408**	**191**

[units: participants]		
Number of Patients With a Clinical Fracture From Baseline to Month 12 [units: Participants]	**10**	**4**

No statistical analysis provided for Number of Patients With a Clinical Fracture From Baseline to Month 12

6. Secondary: Change in Body Height From Baseline to Month 12 [Time Frame: Baseline to end of study (Month 12)]

Measure Type	Secondary
Measure Title	Change in Body Height From Baseline to Month 12
Measure Description	Body height was measured at Baseline and at the end of the study (Month 12) and the change in height calculated.
Time Frame	Baseline to end of study (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.
Intent-to-treat sample (ITT) population: All patients who received at least 1 dose of study medication and who had at least 1 post-baseline determination of cross-linked N-telopeptide of type I collagen (NTx) level.

Reporting Groups

	Description
Zoledronic Acid 5 mg	Patients received zoledronic acid 5 mg in 100 ml solution in a 15 minute intravenous (iv) infusion once per year. The peripheral iv infusion was preceded by and followed by a 10 ml normal saline flush of the intravenous line. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.
Alendronate 70 mg	Patients received an alendronate 70 mg tablet once weekly with 200 ml of tap water in the morning on an empty stomach at least 30 minutes before the first meal. Patients were to remain in an upright position for 30 minutes after swallowing the tablet. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.

Measured Values

	Zoledronic Acid 5 mg	**Alendronate 70 mg**
Number of Participants Analyzed [units: participants]	**408**	**191**
Change in Body Height From Baseline to Month 12 [units: cm] Mean (Standard Deviation)	**-0.1 (1.0)**	**0.0 (1.2)**

No statistical analysis provided for Change in Body Height From Baseline to Month 12

7. Secondary: Therapy Preference at End of Study (Month 12) [Time Frame: Month 12]

Measure Type	Secondary
Measure Title	Therapy Preference at End of Study (Month 12)
Measure Description	Patients were administered a questionnaire at the end of the study in which they were asked which type of therapy, weekly oral or yearly iv, they preferred.
Time Frame	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.
Intent-to-treat sample (ITT) population: All patients who received at least 1 dose of study medication and who had at least 1 post-baseline determination of cross-linked N-telopeptide of type I collagen (NTx) level.

Reporting Groups

	Description
Zoledronic Acid 5 mg	Patients received zoledronic acid 5 mg in 100 ml solution in a 15 minute intravenous (iv) infusion once per year. The peripheral iv infusion was preceded by and followed by a 10 ml normal saline flush of the intravenous line. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.
Alendronate 70 mg	Patients received an alendronate 70 mg tablet once weekly with 200 ml of tap water in the morning on an empty stomach at least 30 minutes before the first meal. Patients were to remain in an upright position for 30 minutes after swallowing the tablet. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.

Measured Values

	Zoledronic Acid 5 mg	Alendronate 70 mg
Number of Participants Analyzed [units: participants]	**408**	**191**
Therapy Preference at End of Study (Month 12) [units: Participants]		
No data available	**30**	**16**
Yearly iv	**330**	**82**
Weekly oral	**48**	**93**

No statistical analysis provided for Therapy Preference at End of Study (Month 12)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Zoledronic Acid 5 mg	Patients received zoledronic acid 5 mg in 100 ml solution in a 15 minute intravenous (iv) infusion once per year. The peripheral iv infusion was preceded by and followed by a 10 ml normal saline flush of the intravenous line. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.
Alendronate 70 mg	Patients received an alendronate 70 mg tablet once weekly with 200 ml of tap water in the morning on an empty stomach at least 30 minutes before the first meal. Patients were to remain in an upright position for 30 minutes after swallowing the tablet. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.

Serious Adverse Events

	Zoledronic Acid 5 mg	Alendronate 70 mg

Total, serious adverse events		
# participants affected / at risk	**43/408 (10.54%)**	**21/194 (10.82%)**
Cardiac disorders		
Angina pectoris † [1]		
# participants affected / at risk	**0/408 (0.00%)**	**1/194 (0.52%)**
Atrial fibrillation † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Atrial flutter † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Bundle branch block left † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Coronary artery insufficiency † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Myocardial infarction † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**1/194 (0.52%)**
Sick sinus syndrome † [1]		
# participants affected / at risk	**0/408 (0.00%)**	**1/194 (0.52%)**
Tachyarrhythmia † [1]		
# participants affected / at risk	**0/408 (0.00%)**	**1/194 (0.52%)**
Ear and labyrinth disorders		
Vestibular disorder † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Endocrine disorders		
Goitre † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Eye disorders		
Visual disturbance † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Gastrointestinal disorders		
Colitis † [1]		
# participants affected / at risk	**0/408 (0.00%)**	**1/194 (0.52%)**
Dyspepsia † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Gastrointestinal haemorrhage † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Vomiting † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
General disorders		
Chest pain † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**1/194 (0.52%)**
Hepatobiliary disorders		
Bile duct stone † [1]		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**

Biliary colic † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Cholecystitis † 1		
# participants affected / at risk	**0/408 (0.00%)**	**1/194 (0.52%)**
Cholestasis † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Infections and infestations		
Gastrointestinal infection † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Herpes zoster † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Pneumonia † 1		
# participants affected / at risk	**2/408 (0.49%)**	**0/194 (0.00%)**
Injury, poisoning and procedural complications		
Concussion † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Facial bones fracture † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Fall † 1		
# participants affected / at risk	**1/408 (0.25%)**	**1/194 (0.52%)**
Femur fracture † 1		
# participants affected / at risk	**0/408 (0.00%)**	**1/194 (0.52%)**
Foot fracture † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Forearm fracture † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Meniscus lesion † 1		
# participants affected / at risk	**2/408 (0.49%)**	**0/194 (0.00%)**
Wrist fracture † 1		
# participants affected / at risk	**0/408 (0.00%)**	**1/194 (0.52%)**
Investigations		
C-Reactive protein increased † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Diabetes mellitus † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Hyponatraemia † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**0/408 (0.00%)**	**1/194 (0.52%)**
Back pain † 1		

# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Foot deformity † [1]		
# participants affected / at risk	0/408 (0.00%)	1/194 (0.52%)
Intervertebral disc protrusion † [1]		
# participants affected / at risk	1/408 (0.25%)	1/194 (0.52%)
Osteoarthritis † [1]		
# participants affected / at risk	2/408 (0.49%)	0/194 (0.00%)
Polymyalgia rheumatica † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Rheumatoid arthritis † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Rotator cuff syndrome † [1]		
# participants affected / at risk	0/408 (0.00%)	3/194 (1.55%)
Spinal column stenosis † [1]		
# participants affected / at risk	0/408 (0.00%)	1/194 (0.52%)
Spinal osteoarthritis † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Adenocarcinoma † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Breast cancer † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Ovarian cancer † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Nervous system disorders		
Cerebrovascular vascular accident † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Dizziness † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Facial palsy † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Headache † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Lo of consciousness † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Monoplegia † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Presenile dementia † [1]		
# participants affected / at risk	1/408 (0.25%)	0/194 (0.00%)
Syncope † [1]		
# participants affected / at risk	1/408 (0.25%)	2/194 (1.03%)
Transient ischaemic attack † [1]		
# participants affected / at risk	2/408 (0.49%)	0/194 (0.00%)
Pregnancy, puerperium and perinatal conditions		

Postpartum haemorrhage † 1		
# participants affected / at risk	**0/408 (0.00%)**	**1/194 (0.52%)**
Renal and urinary disorders		
Nephrolithiasis † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Reproductive system and breast disorders		
Uterine cyst † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Uterine prolapse † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Dyspnoea † 1		
# participants affected / at risk	**3/408 (0.74%)**	**0/194 (0.00%)**
Pulmonary congestion † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Pulmonary embolism † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Skin and subcutaneous tissue disorders		
Urticaria † 1		
# participants affected / at risk	**0/408 (0.00%)**	**1/194 (0.52%)**
Surgical and medical procedures		
Arterial bypass operation † 1		
# participants affected / at risk	**0/408 (0.00%)**	**1/194 (0.52%)**
Vascular disorders		
Arterial occlusive disease † 1		
# participants affected / at risk	**1/408 (0.25%)**	**0/194 (0.00%)**
Circulatory collapse † 1		
# participants affected / at risk	**0/408 (0.00%)**	**3/194 (1.55%)**
Femoral artery occlusion † 1		
# participants affected / at risk	**0/408 (0.00%)**	**1/194 (0.52%)**
Hypertensive crisis † 1		
# participants affected / at risk	**1/408 (0.25%)**	**2/194 (1.03%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.X

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Zoledronic Acid 5 mg	Patients received zoledronic acid 5 mg in 100 ml solution in a 15 minute intravenous (iv) infusion once per year. The peripheral iv infusion was preceded by and followed by a 10 ml normal saline flush of the intravenous line. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.
Alendronate 70 mg	Patients received an alendronate 70 mg tablet once weekly with 200 ml of tap water in the morning on an empty stomach at least 30 minutes before the first meal. Patients were to remain in an upright position for 30 minutes after swallowing the tablet. In addition to study therapy, all participants received 1200 mg elemental calcium and 800 IU of vitamin D daily. Calcium and vitamin D were supplied in a chewable tablet that was to be taken twice daily.

Other Adverse Events

	Zoledronic Acid 5 mg	Alendronate 70 mg
Total, other (not including serious) adverse events		
# participants affected / at risk	**267/408 (65.44%)**	**94/194 (48.45%)**
Gastrointestinal disorders		
Abdominal pain upper † [1]		
# participants affected / at risk	**12/408 (2.94%)**	**13/194 (6.70%)**
Constipation † [1]		
# participants affected / at risk	**9/408 (2.21%)**	**10/194 (5.15%)**
Diarrhoea † [1]		
# participants affected / at risk	**9/408 (2.21%)**	**10/194 (5.15%)**
Dyspepsia † [1]		
# participants affected / at risk	**3/408 (0.74%)**	**14/194 (7.22%)**
Nausea † [1]		
# participants affected / at risk	**23/408 (5.64%)**	**11/194 (5.67%)**
General disorders		
Fatigue † [1]		
# participants affected / at risk	**24/408 (5.88%)**	**4/194 (2.06%)**
Influenza like illness † [1]		
# participants affected / at risk	**132/408 (32.35%)**	**5/194 (2.58%)**
Pyrexia † [1]		
# participants affected / at risk	**21/408 (5.15%)**	**2/194 (1.03%)**
Infections and infestations		
Nasopharyngitis † [1]		
# participants affected / at risk	**26/408 (6.37%)**	**23/194 (11.86%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † [1]		
# participants affected / at risk	**55/408 (13.48%)**	**21/194 (10.82%)**
Back pain † [1]		
# participants affected / at risk	**52/408 (12.75%)**	**20/194 (10.31%)**
Bone pain † [1]		
# participants affected / at risk	**23/408 (5.64%)**	**7/194 (3.61%)**

Pain in extremity † 1		
# participants affected / at risk	**30/408 (7.35%)**	**5/194 (2.58%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**43/408 (10.54%)**	**8/194 (4.12%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.X

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

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

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

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

Restriction Description: The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (ie, data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862 778-8300

No publications provided

Responsible Party:	External Affairs, Novartis
ClinicalTrials.gov Identifier:	NCT00404820 History of Changes
Other Study ID Numbers:	**CZOL446HDE31**
Study First Received:	November 28, 2006
Results First Received:	January 5, 2011
Last Updated:	June 6, 2011
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices