Trial record **1 of 1** for: CZOL446N2312
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Zoledronic Acid in the Prevention of Bone Loss in Postmenopausal Women With Osteopenia, 45 Years of Age and Older

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00132808

First received: August 18, 2005
Last updated: July 31, 2012
Last verified: July 2012
History of Changes

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Results First Received: December 10, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Osteopenia
Interventions:	Drug: Zoledronic Acid Drug: Placebo

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
Eligible patients were stratified according to their duration of menopause (those less than 5 years from menopause were included in Stratum I, while those 5 or more years from menopause were included in Stratum II), and randomized equally to one of the three treatment groups.

Reporting Groups

	Description
Zoledronic Acid 2x5 mg	Zoledronic acid 5 mg intravenous (i.v.) given at randomization and Month 12
Zoledronic Acid 1x5 mg	Zoledronic acid 5 mg i.v. given at randomization and placebo at Month 12
Placebo	Placebo given at randomization and Month 12

Participant Flow for 2 periods

Period 1: Stratum I

	Zoledronic Acid 2x5 mg	Zoledronic Acid 1x5 mg	Placebo
STARTED	77	70	77
COMPLETED	68	58	72
NOT COMPLETED	9	12	5
Adverse Event	2	1	0
Lost to Follow-up	3	4	1
Withdrawal by Subject	4	7	3
Abnormal test procedure result (s)	0	0	1

Period 2: Stratum II

	Zoledronic Acid 2x5 mg	Zoledronic Acid 1x5 mg	Placebo
STARTED	121	111	125
COMPLETED	113	96	116
NOT COMPLETED	8	15	9
Adverse Event	1	2	1
Death	1	0	0
Lost to Follow-up	2	2	1
Protocol Violation	0	2	1
Withdrawal by Subject	4	9	6

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 2x5 mg	Zoledronic acid 5 mg intravenous (i.v.) given at randomization and Month 12
Zoledronic Acid 1x5 mg	Zoledronic acid 5 mg i.v. given at randomization and placebo at Month 12
Placebo	Placebo given at randomization and Month 12
Total	Total of all reporting groups

Baseline Measures

	Zoledronic Acid 2x5 mg	Zoledronic Acid 1x5 mg	Placebo	Total
Number of Participants [units: participants]	198	181	202	581
Age [units: years] Mean (Standard Deviation)				
Stratum I (Women < 5 Years From Menopause)	53.6 (3.62)	53.7 (3.59)	54.4 (3.83)	53.9 (3.68)
	63.9 (6.62)	63.4 (7.74)		

Stratum II (Women >= 5 Years From Menopause)			**64.2 (7.65)**	**63.8 (7.34)**
Gender [1] [units: participants]				
Female	**198**	**181**	**202**	**581**
Male	**0**	**0**	**0**	**0**

[1] Data presented for Overall number of Participants and Gender include participants from both strata of the study.

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage Change in Lumbar Spine Bone Mineral Density (BMD) at Month 24 Relative to Baseline, by Stratum [Time Frame: Baseline, Month 24]

Measure Type	Primary
Measure Title	Percentage Change in Lumbar Spine Bone Mineral Density (BMD) at Month 24 Relative to Baseline, by Stratum
Measure Description	The percentage change in lumbar spine BMD at Month 24 relative to baseline was derived as 100 x (lumbar spine BMD at 24 Month – lumbar spine BMD at baseline) / (lumbar spine BMD at baseline).
Time Frame	Baseline, Month 24
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 population. Last observation carried forward (LOCF) was utilized to impute missing data.

Reporting Groups

	Description
Zoledronic Acid 2x5 mg	Zoledronic acid 5 mg intravenous (i.v.) given at randomization and Month 12
Zoledronic Acid 1x5 mg	Zoledronic acid 5 mg i.v. given at randomization and placebo at Month 12
Placebo	Placebo given at randomization and Month 12

Measured Values

	Zoledronic Acid 2x5 mg	**Zoledronic Acid 1x5 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**198**	**181**	**202**
Percentage Change in Lumbar Spine Bone Mineral Density (BMD) at Month 24 Relative to Baseline, by Stratum [units: Percentage change in BMD] Least Squares Mean (Standard Error)			
Stratum I (Women < 5 Years From Menopause)	**4.62 (0.444)**	**4.03 (0.444)**	**-2.24 (0.428)**
Stratum II (Women >= 5 Years From Menopause)	**5.60 (0.343)**	**4.76 (0.356)**	**-0.65 (0.339)**

No statistical analysis provided for Percentage Change in Lumbar Spine Bone Mineral Density (BMD) at Month 24 Relative to Baseline, by Stratum

2. Secondary: Percentage Change in Total Hip BMD at Month 24 Relative to Baseline, by Stratum. [Time Frame: Baseline, Month 24]

Measure Type	Secondary
Measure Title	Percentage Change in Total Hip BMD at Month 24 Relative to Baseline, by Stratum.
Measure Description	The percentage change in total hip BMD at Month 24 relative to baseline was derived as 100 x (total hip BMD at 24 Month - total hip BMD at baseline) / (total hip BMD at baseline).
Time Frame	Baseline, Month 24
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 population with available data.

Reporting Groups

	Description
Zoledronic Acid 2x5 mg	Zoledronic acid 5 mg intravenous (i.v.) given at randomization and Month 12
Zoledronic Acid 1x5 mg	Zoledronic acid 5 mg i.v. given at randomization and placebo at Month 12
Placebo	Placebo given at randomization and Month 12

Measured Values

	Zoledronic Acid 2x5 mg	**Zoledronic Acid 1x5 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**198**	**181**	**202**
Percentage Change in Total Hip BMD at Month 24 Relative to Baseline, by Stratum. [units: Percentage change in BMD] Least Squares Mean (Standard Error)			
Stratum I (Women < 5 Years From Menopause)	**2.66 (0.318)**	**2.55 (0.317)**	**-2.10 (0.293)**
Stratum II (Women >= 5 Years From Menopause)	**3.04 (0.265)**	**2.11 (0.282)**	**-1.04 (0.265)**

No statistical analysis provided for Percentage Change in Total Hip BMD at Month 24 Relative to Baseline, by Stratum.

3. Secondary: Percentage Change in Femoral Neck BMD at Month 24 Relative to Baseline, by Stratum. [Time Frame: Baseline, Month 24]

Measure Type	Secondary
Measure Title	Percentage Change in Femoral Neck BMD at Month 24 Relative to Baseline, by Stratum.
Measure Description	The percentage change in femoral neck BMD at Month 24 relative to baseline was derived as 100 x (femoral neck BMD at 24 Month - femoral neck BMD at baseline) / (femoral neck BMD at baseline).
Time Frame	Baseline, Month 24
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 population with available data.

Reporting Groups

	Description
Zoledronic Acid 2x5 mg	Zoledronic acid 5 mg intravenous (i.v.) given at randomization and Month 12
Zoledronic Acid 1x5 mg	Zoledronic acid 5 mg i.v. given at randomization and placebo at Month 12
Placebo	Placebo given at randomization and Month 12

Measured Values

	Zoledronic Acid 2x5 mg	Zoledronic Acid 1x5 mg	Placebo
Number of Participants Analyzed [units: participants]	**198**	**181**	**202**
Percentage Change in Femoral Neck BMD at Month 24 Relative to Baseline, by Stratum. [units: Percentage change in BMD] Least Squares Mean (Standard Error)			
Stratum I (Women < 5 Years From Menopause)	**2.04 (0.550)**	**2.01 (0.549)**	**-1.55 (0.508)**
Stratum II (Women >= 5 Years From Menopause)	**2.35 (0.344)**	**1.46 (0.366)**	**-1.18 (0.343)**

No statistical analysis provided for Percentage Change in Femoral Neck BMD at Month 24 Relative to Baseline, by Stratum.

4. Secondary: Biochemical Marker of Bone Resorption: Serum Beta C-telopeptides (b-CTx), by Stratum [Time Frame: Months 6, 12, 18 and 24]

Measure Type	Secondary
Measure Title	Biochemical Marker of Bone Resorption: Serum Beta C-telopeptides (b-CTx), by Stratum
Measure Description	Biomarker: Serum b-CTx levels at Months 6, 12, 18 and 24 by stratum.
Time Frame	Months 6, 12, 18 and 24
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.
Intent to treat population with available data.

Reporting Groups

	Description
Zoledronic Acid 2x5 mg	Zoledronic acid 5 mg intravenous (i.v.) given at randomization and Month 12
Zoledronic Acid 1x5 mg	Zoledronic acid 5 mg i.v. given at randomization and placebo at Month 12
Placebo	Placebo given at randomization and Month 12

Measured Values

	Zoledronic Acid 2x5 mg	Zoledronic Acid 1x5 mg	Placebo
Number of Participants Analyzed [units: participants]	**198**	**181**	**202**

Biochemical Marker of Bone Resorption: Serum Beta C-telopeptides (b-CTx), by Stratum [units: ng/mL] Mean (Standard Deviation)			
Stratum I - Month 6	**0.2217 (0.11791)**	**0.2286 (0.09630)**	**0.6439 (0.27902)**
Stratum I - Month 12	**0.2861 (0.13776)**	**0.3111 (0.13195)**	**0.6634 (0.25433)**
Stratum I - Month 18	**0.2187 (0.16812)**	**0.3605 (0.14847)**	**0.6444 (0.28254)**
Stratum I - Month 24	**0.2864 (0.12242)**	**0.3777 (0.14943)**	**0.6640 (0.27538)**
Stratum II - Month 6	**0.1918 (0.12648)**	**0.1888 (0.10625)**	**0.5802 (0.25034)**
Stratum II - Month 12	**0.2696 (0.18247)**	**0.2484 (0.11435)**	**0.5634 (0.23442)**
Stratum II - Month 18	**0.1986 (0.14900)**	**0.2854 (0.14391)**	**0.5742 (0.24399)**
Stratum II - Month 24	**0.2554 (0.17049)**	**0.3254 (0.15260)**	**0.6012 (0.26942)**

No statistical analysis provided for Biochemical Marker of Bone Resorption: Serum Beta C-telopeptides (b-CTx), by Stratum

5. Secondary: Biochemical Marker of Bone Formation: Serum N-terminal Propeptide of Type 1 Collagen (P1NP), by Stratum [Time Frame: Months 6, 12, 18 and 24]

Measure Type	Secondary
Measure Title	Biochemical Marker of Bone Formation: Serum N-terminal Propeptide of Type 1 Collagen (P1NP), by Stratum
Measure Description	Biomarker: Serum P1NP levels at Months 6, 12, 18 and 24 by stratum.
Time Frame	Months 6, 12, 18 and 24
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.
Intent to treat population with available data.

Reporting Groups

	Description
Zoledronic Acid 2x5 mg	Zoledronic acid 5 mg intravenous (i.v.) given at randomization and Month 12
Zoledronic Acid 1x5 mg	Zoledronic acid 5 mg i.v. given at randomization and placebo at Month 12
Placebo	Placebo given at randomization and Month 12

Measured Values

	Zoledronic Acid 2x5 mg	**Zoledronic Acid 1x5 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**198**	**181**	**202**
Biochemical Marker of Bone Formation: Serum N-terminal Propeptide of Type 1 Collagen (P1NP), by Stratum			

[units: ng/mL] Mean (Standard Deviation)			
Stratum I - Month 6	20.851 (9.7724)	20.752 (9.7560)	59.449 (20.3291)
Stratum I - Month 12	28.231 (12.3748)	30.500 (14.8217)	55.166 (20.5274)
Stratum I - Month 18	20.102 (12.6635)	35.561 (14.1588)	55.775 (19.8842)
Stratum I - Month 24	28.288 (12.2706)	38.743 (14.7626)	56.315 (20.3715)
Stratum II - Month 6	19.369 (14.1819)	19.423 (16.6028)	50.271 (22.6624)
Stratum II - Month 12	28.333 (15.8193)	26.363 (13.1112)	49.581 (20.6559)
Stratum II - Month 18	19.031 (14.8270)	29.569 (14.7631)	46.943 (18.8147)
Stratum II - Month 24	26.211 (11.8566)	34.418 (15.4474)	51.621 (20.9281)

No statistical analysis provided for Biochemical Marker of Bone Formation: Serum N-terminal Propeptide of Type 1 Collagen (P1NP), by Stratum

6. Secondary: Biochemical Marker of Bone Formation: Bone Serum Alkaline Phosphatase (BSAP), by Stratum [Time Frame: Months 6, 12, 18 and 24]

Measure Type	Secondary
Measure Title	Biochemical Marker of Bone Formation: Bone Serum Alkaline Phosphatase (BSAP), by Stratum
Measure Description	Biomarker: BSAP levels at Months 6, 12, 18 and 24 by stratum.
Time Frame	Months 6, 12, 18 and 24
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.
Intent to treat population with available data.

Reporting Groups

	Description
Zoledronic Acid 2x5 mg	Zoledronic acid 5 mg intravenous (i.v.) given at randomization and Month 12
Zoledronic Acid 1x5 mg	Zoledronic acid 5 mg i.v. given at randomization and placebo at Month 12
Placebo	Placebo given at randomization and Month 12

Measured Values

	Zoledronic Acid 2x5 mg	**Zoledronic Acid 1x5 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**198**	**181**	**202**
Biochemical Marker of Bone Formation: Bone Serum Alkaline Phosphatase (BSAP), by Stratum [units: ng/mL] Mean (Standard Deviation)			

Stratum I - Month 6	8.718 (2.5827)	8.841 (2.2434)	13.982 (4.7106)
Stratum I - Month 12	9.945 (2.9027)	10.539 (2.9800)	14.127 (4.8981)
Stratum I - Month 18	8.365 (2.5574)	11.233 (3.1563)	14.149 (4.8878)
Stratum I - Month 24	9.799 (2.5836)	11.764 (3.8401)	14.353 (4.9089)
Stratum II - Month 6	8.219 (2.8126)	7.925 (2.2847)	13.394 (5.2169)
Stratum II - Month 12	9.678 (3.0216)	9.139 (2.4558)	13.650 (4.8295)
Stratum II - Month 18	8.357 (2.2152)	10.023 (2.8237)	13.222 (4.9167)
Stratum II - Month 24	9.730 (2.7591)	10.916 (3.5878)	13.902 (4.6302)

No statistical analysis provided for Biochemical Marker of Bone Formation: Bone Serum Alkaline Phosphatase (BSAP), by Stratum

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Zoledronic Acid 2x5 mg	Zoledronic acid 5 mg intravenous (i.v.) given at randomization and Month 12
Zoledronic Acid 1x5 mg	Zoledronic acid 5 mg i.v. given at randomization and placebo at Month 12
Placebo	Placebo given at randomization and Month 12

Serious Adverse Events

	Zoledronic Acid 2x5 mg	Zoledronic Acid 1x5 mg	Placebo
Total, serious adverse events			
# participants affected / at risk	21/198 (10.61%)	17/181 (9.39%)	23/202 (11.39%)
Cardiac disorders			
Angina pectoris † 1			
# participants affected / at risk	2/198 (1.01%)	1/181 (0.55%)	1/202 (0.50%)
Endocrine disorders			
Thyroid mass † 1			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Eye disorders			
Cataract † 1			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Gastrointestinal disorders			

Abdominal pain [†1]			
# participants affected / at risk	2/198 (1.01%)	0/181 (0.00%)	1/202 (0.50%)
Crohn's disease [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Diverticulum intestinal [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Duodenal ulcer haemorrhage [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Dyspepsia [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Gastrooesophageal reflux disease [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Hiatus hernia [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Ileus [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Ileus paralytic [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Intestinal polyp [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Intestinal prolapse [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Large intestine perforation [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Nausea [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Pancreatitis [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Rectal haemorrhage [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Rectal prolapse [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Vomiting [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
General disorders			
Non-cardiac chest pain [†1]			
# participants affected / at risk	2/198 (1.01%)	3/181 (1.66%)	1/202 (0.50%)
Hepatobiliary disorders			
Cholecystitis [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Immune system disorders			
Hypersensitivity [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Infections and infestations			
Bronchitis [†1]			

# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Cystitis [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Osteomyelitis [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Parotitis [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Pelvic abscess [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Sepsis [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Sinusitis [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Injury, poisoning and procedural complications			
Collapse of lung [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Femur fracture [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Subdural haematoma [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Wrist fracture [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Metabolism and nutrition disorders			
Dehydration [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Hypocalcaemia [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Hyponatraemia [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Musculoskeletal and connective tissue disorders			
Arthralgia [†1]			
# participants affected / at risk	0/198 (0.00%)	2/181 (1.10%)	0/202 (0.00%)
Arthritis [†1]			
# participants affected / at risk	1/198 (0.51%)	1/181 (0.55%)	0/202 (0.00%)
Intervertebral disc protrusion [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Loose body in joint [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Lumbar spinal stenosis [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Osteoarthritis [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Osteonecrosis [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Pain in extremity [†1]			

# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Tendon disorder [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Breast cancer [†1]			
# participants affected / at risk	1/198 (0.51%)	1/181 (0.55%)	1/202 (0.50%)
Cardiac neoplasm unspecified [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Colon cancer [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Laryngeal cancer [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Malignant melanoma [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Malignant peritoneal neoplasm [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Metastases to spine [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Metastatic neoplasm [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Nasopharyngeal cancer [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Neurilemmoma [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Ovarian cancer [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Pleural mesothelioma malignant [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Nervous system disorders			
Cerebral haemorrhage [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Convulsion [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Encephalopathy [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Global amnesia [†1]			
# participants affected / at risk	1/198 (0.51%)	0/181 (0.00%)	0/202 (0.00%)
Hypoaesthesia [†1]			
# participants affected / at risk	0/198 (0.00%)	0/181 (0.00%)	1/202 (0.50%)
Lumbar radiculopathy [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	0/202 (0.00%)
Syncope [†1]			
# participants affected / at risk	0/198 (0.00%)	1/181 (0.55%)	2/202 (0.99%)

Psychiatric disorders			
Bipolar disorder † 1			
# participants affected / at risk	**0/198 (0.00%)**	**1/181 (0.55%)**	**0/202 (0.00%)**
Depression † 1			
# participants affected / at risk	**0/198 (0.00%)**	**0/181 (0.00%)**	**1/202 (0.50%)**
Psychotic disorder † 1			
# participants affected / at risk	**1/198 (0.51%)**	**0/181 (0.00%)**	**0/202 (0.00%)**
Renal and urinary disorders			
Bladder prolapse † 1			
# participants affected / at risk	**1/198 (0.51%)**	**0/181 (0.00%)**	**0/202 (0.00%)**
Pollakiuria † 1			
# participants affected / at risk	**1/198 (0.51%)**	**0/181 (0.00%)**	**0/202 (0.00%)**
Renal failure acute † 1			
# participants affected / at risk	**1/198 (0.51%)**	**0/181 (0.00%)**	**0/202 (0.00%)**
Reproductive system and breast disorders			
Endometrial metaplasia † 1			
# participants affected / at risk	**1/198 (0.51%)**	**0/181 (0.00%)**	**0/202 (0.00%)**
Uterine prolapse † 1			
# participants affected / at risk	**0/198 (0.00%)**	**0/181 (0.00%)**	**1/202 (0.50%)**
Respiratory, thoracic and mediastinal disorders			
Asthma † 1			
# participants affected / at risk	**0/198 (0.00%)**	**0/181 (0.00%)**	**1/202 (0.50%)**
Pneumothorax † 1			
# participants affected / at risk	**0/198 (0.00%)**	**0/181 (0.00%)**	**1/202 (0.50%)**
Pulmonary embolism † 1			
# participants affected / at risk	**0/198 (0.00%)**	**0/181 (0.00%)**	**1/202 (0.50%)**
Vascular disorders			
Arterial occlusive disease † 1			
# participants affected / at risk	**1/198 (0.51%)**	**0/181 (0.00%)**	**0/202 (0.00%)**
Hypertension † 1			
# participants affected / at risk	**1/198 (0.51%)**	**0/181 (0.00%)**	**0/202 (0.00%)**
Leriche syndrome † 1			
# participants affected / at risk	**1/198 (0.51%)**	**0/181 (0.00%)**	**0/202 (0.00%)**
Varicose vein † 1			
# participants affected / at risk	**1/198 (0.51%)**	**0/181 (0.00%)**	**0/202 (0.00%)**

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

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 2x5 mg	Zoledronic acid 5 mg intravenous (i.v.) given at randomization and Month 12
Zoledronic Acid 1x5 mg	Zoledronic acid 5 mg i.v. given at randomization and placebo at Month 12
Placebo	Placebo given at randomization and Month 12

Other Adverse Events

	Zoledronic Acid 2x5 mg	Zoledronic Acid 1x5 mg	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**177/198 (89.39%)**	**158/181 (87.29%)**	**160/202 (79.21%)**
Gastrointestinal disorders			
Abdominal pain [†1]			
# participants affected / at risk	**11/198 (5.56%)**	**6/181 (3.31%)**	**6/202 (2.97%)**
Constipation [†1]			
# participants affected / at risk	**13/198 (6.57%)**	**13/181 (7.18%)**	**14/202 (6.93%)**
Diarrhoea [†1]			
# participants affected / at risk	**16/198 (8.08%)**	**12/181 (6.63%)**	**16/202 (7.92%)**
Dyspepsia [†1]			
# participants affected / at risk	**13/198 (6.57%)**	**12/181 (6.63%)**	**10/202 (4.95%)**
Gastrooesophageal reflux disease [†1]			
# participants affected / at risk	**9/198 (4.55%)**	**5/181 (2.76%)**	**12/202 (5.94%)**
Nausea [†1]			
# participants affected / at risk	**34/198 (17.17%)**	**21/181 (11.60%)**	**16/202 (7.92%)**
Vomiting [†1]			
# participants affected / at risk	**14/198 (7.07%)**	**9/181 (4.97%)**	**9/202 (4.46%)**
General disorders			
Asthenia [†1]			
# participants affected / at risk	**12/198 (6.06%)**	**5/181 (2.76%)**	**2/202 (0.99%)**
Chills [†1]			
# participants affected / at risk	**36/198 (18.18%)**	**33/181 (18.23%)**	**6/202 (2.97%)**
Fatigue [†1]			
# participants affected / at risk	**29/198 (14.65%)**	**18/181 (9.94%)**	**8/202 (3.96%)**
Non-cardiac chest pain [†1]			
# participants affected / at risk	**6/198 (3.03%)**	**12/181 (6.63%)**	**6/202 (2.97%)**
Oedema peripheral [†1]			
# participants affected / at risk	**11/198 (5.56%)**	**7/181 (3.87%)**	**7/202 (3.47%)**
Pain [†1]			
# participants affected / at risk	**48/198 (24.24%)**	**27/181 (14.92%)**	**7/202 (3.47%)**
Pyrexia [†1]			
# participants affected / at risk	**43/198 (21.72%)**	**38/181 (20.99%)**	**9/202 (4.46%)**
Infections and infestations			

Bronchitis [†1]			
# participants affected / at risk	12/198 (6.06%)	14/181 (7.73%)	22/202 (10.89%)
Influenza [†1]			
# participants affected / at risk	12/198 (6.06%)	15/181 (8.29%)	12/202 (5.94%)
Nasopharyngitis [†1]			
# participants affected / at risk	27/198 (13.64%)	17/181 (9.39%)	23/202 (11.39%)
Sinusitis [†1]			
# participants affected / at risk	16/198 (8.08%)	12/181 (6.63%)	24/202 (11.88%)
Upper respiratory tract infection [†1]			
# participants affected / at risk	27/198 (13.64%)	19/181 (10.50%)	23/202 (11.39%)
Urinary tract infection [†1]			
# participants affected / at risk	22/198 (11.11%)	16/181 (8.84%)	25/202 (12.38%)
Metabolism and nutrition disorders			
Hypercholesterolaemia [†1]			
# participants affected / at risk	7/198 (3.54%)	10/181 (5.52%)	4/202 (1.98%)
Musculoskeletal and connective tissue disorders			
Arthralgia [†1]			
# participants affected / at risk	54/198 (27.27%)	34/181 (18.78%)	39/202 (19.31%)
Back pain [†1]			
# participants affected / at risk	36/198 (18.18%)	30/181 (16.57%)	24/202 (11.88%)
Bone pain [†1]			
# participants affected / at risk	10/198 (5.05%)	6/181 (3.31%)	2/202 (0.99%)
Muscle spasms [†1]			
# participants affected / at risk	11/198 (5.56%)	5/181 (2.76%)	10/202 (4.95%)
Musculoskeletal pain [†1]			
# participants affected / at risk	11/198 (5.56%)	10/181 (5.52%)	11/202 (5.45%)
Myalgia [†1]			
# participants affected / at risk	38/198 (19.19%)	41/181 (22.65%)	14/202 (6.93%)
Neck pain [†1]			
# participants affected / at risk	10/198 (5.05%)	12/181 (6.63%)	10/202 (4.95%)
Osteoarthritis [†1]			
# participants affected / at risk	5/198 (2.53%)	3/181 (1.66%)	16/202 (7.92%)
Pain in extremity [†1]			
# participants affected / at risk	22/198 (11.11%)	29/181 (16.02%)	20/202 (9.90%)
Nervous system disorders			
Dizziness [†1]			
# participants affected / at risk	15/198 (7.58%)	11/181 (6.08%)	7/202 (3.47%)
Headache [†1]			
# participants affected / at risk	29/198 (14.65%)	37/181 (20.44%)	23/202 (11.39%)
Hypoaesthesia [†1]			
# participants affected / at risk	11/198 (5.56%)	4/181 (2.21%)	3/202 (1.49%)
Psychiatric disorders			
Insomnia [†1]			
# participants affected / at risk	6/198 (3.03%)	5/181 (2.76%)	12/202 (5.94%)
Respiratory, thoracic and mediastinal disorders			

Cough † 1			
# participants affected / at risk	**17/198 (8.59%)**	**11/181 (6.08%)**	**10/202 (4.95%)**
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	**9/198 (4.55%)**	**15/181 (8.29%)**	**14/202 (6.93%)**

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

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 (i.e., 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 by Novartis

Publications automatically indexed to this study:

Grbic JT, Black DM, Lyles KW, Reid DM, Orwoll E, McClung M, Bucci-Rechtweg C, Su G. The incidence of osteonecrosis of the jaw in patients receiving 5 milligrams of zoledronic acid: data from the health outcomes and reduced incidence with zoledronic acid once yearly clinical trials program. J Am Dent Assoc. 2010 Nov;141(11):1365-70.

McClung M, Miller P, Recknor C, Mesenbrink P, Bucci-Rechtweg C, Benhamou CL. Zoledronic acid for the prevention of bone loss in postmenopausal women with low bone mass: a randomized controlled trial. Obstet Gynecol. 2009 Nov;114(5):999-1007. doi: 10.1097/AOG.0b013e3181bdce0a.

Responsible Party: Novartis (Novartis Pharmaceuticals)

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Other Study ID Numbers:	**CZOL446N2312**
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Results First Received:	December 10, 2010
Last Updated:	July 31, 2012
Health Authority:	United States: Food and Drug Administration