Sequential Treatment of Postmenopausal Women With Primary Osteoporosis (FP-001-IM) (PEAK)

This study has been completed.

Sponsor:
Takeda

Information provided by (Responsible Party):
Takeda

ClinicalTrials.gov Identifier:
NCT00365456

First received: August 9, 2006
Last updated: August 16, 2012
Last verified: August 2012
History of Changes

Results First Received: May 4, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Osteoporosis
Interventions:	Drug: Parathyroid Hormone (PTH) Drug: Risedronate

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 trial was divided into 3 consecutive open-label treatment phases of 12 months with randomisation after Trial Period II.

From 407 enrolled patients in total, 2 patients were enrolled but were never exposed to trial treatment. Thus, 405 patients in total received trial treatment.

Pre-Assignment Details

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

- Period I: total number of 405 patients were included and all received PTH(1-84) treatment for 1 year
- Period II: of those 405 patients, 282 continued into the 2. year and all received risedronate
- Period III: during the 3. year, the remaining 268 patients were randomised to either PTH(1-84) (=136 patients) or risedronate (=132 patients)

Reporting Groups

	Description
PTH (1-84)	No text entered.
Risedronate	No text entered.

Participant Flow for 3 periods

Period 1: Trial Period I (12 Months)

	PTH (1-84)	Risedronate
STARTED	407	0
COMPLETED	282	0
NOT COMPLETED	125	0
Adverse Event	84	0
Non-compliance	3	0
Withdrawal by Subject	27	0
Unknown	11	0

Period 2: Trial Period II (12 Months)

	PTH (1-84)	Risedronate
STARTED	0	282
COMPLETED	0	268
NOT COMPLETED	0	14
Adverse Event	0	6
Non-compliance	0	2
Withdrawal by Subject	0	5
Other	0	1

Period 3: Trial Period III (12 Months)

	PTH (1-84)	Risedronate
STARTED	136	132
COMPLETED	118	127
NOT COMPLETED	18	5
Adverse Event	13	3
Withdrawal by Subject	4	1
Other	1	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
PTH(1-84) or Risedronate	• PTH(1-84) received by 405 participants in Trial Period I • of those 405 participants, 282 received Risedronate in Trial Period II • of those 282 participants, 268 participant remained and 136 received PTH(1-84) and 132 received Risedronate in Trial Period III

Baseline Measures

	PTH(1-84) or Risedronate
Number of Participants [units: participants]	**405**
Age, Customized [units: years] Mean (Standard Deviation)	
Trial Period I / PTH(1-84)	**64.6 (7.46)**
Trial Period II / Risedronate	**64.2 (7.43)**
Trial Period III / PTH(1-84)	**63.4 (6.94)**
Trial Period III / Risedronate	**64.7 (7.91)**
Gender, Customized [units: participants]	
female	**405**
Lumbar spine T-score [1] [units: score] Mean (Standard Deviation)	
Trial Period I / PTH(1-84)	**-3.61 (0.490)**
Trial Period II / Risedronate	**-3.62 (0.472)**
Trial Period III / PTH(1-84)	**-3.60 (0.427)**
Trial Period III / Risedronate	**-3.63 (0.518)**
Prevalent vertebral fractures [2] [units: participants]	
Trial Period I / PTH(1-84)	**105**
Trial Period II / Risedronate	**71**
Trial Period III / PTH(1-84)	**37**
Trial Period III / Risedronate	**29**
Prevalent non-vertebral fragility fractures [units: participants]	
Trial Period I / PTH(1-84): hip fractures	**9**
Trial Period II / Risedronate: hip fractures	**5**
Trial Period III / PTH(1-84): hip fractures	**1**

Trial Period III / Risedronate: hip fractures	3
Trial Period I / PTH(1-84): wrist fractures	78
Trial Period II / Risedronate: wrist fractures	50
Trial Period III / PTH(1-84): wrist fractures	22
Trial Period III / Risedronate: wrist fractures	25
Trial Period I / PTH(1-84): others	93
Trial Period II / Risedronate: others	59
Trial Period III / PTH(1-84): others	28
Trial Period III / Risedronate: others	27
Weight **[units: kg]** **Mean (Standard Deviation)**	
Trial Period I / PTH(1-84)	59.5 (9.39)
Trial Period II / Risedronate	59.7 (9.17)
Trial Period III / PTH(1-84)	59.6 (8.66)
Trial Period III / Risedronate	59.8 (9.57)
Height **[units: cm]** **Mean (Standard Deviation)**	
Trial Period I / PTH(1-84)	157.4 (6.40)
Trial Period II / Risedronate	157.5 (6.48)
Trial Period III / PTH(1-84)	157.6 (6.21)
Trial Period III / Risedronate	157.4 (6.86)
Serum Calcium **[units: mmol/L]** **Mean (Standard Deviation)**	
Trial Period I / PTH(1-84)	2.338 (0.1022)
Trial Period II / Risedronate	2.337 (0.0999)
Trial Period III / PTH(1-84)	2.337 (0.0961)
Trial Period III / Risedronate	2.339 (0.1041)
Body Mass Index **[units: kg/m^2]** **Mean (Standard Deviation)**	
Trial Period I / PTH(1-84)	24.06 (3.861)
Trial Period II / Risedronate	24.11 (3.788)
Trial Period III / PTH(1-84)	24.06 (3.618)
Trial Period III / Risedronate	24.21 (3.933)

[1] The T-score represents the lumbar spine bone mineral density as compared to a young normal reference mean (healthy 30-year-old woman). A score ≥ -1.0 is considered Normal, while a score between -1.0 and -2.5 is defined as Osteopenia and a score ≤ -2.5 is defined as Osteoporosis.

[2] Number of patients with at least one vertebral fracture at baseline

Outcome Measures

1. Primary: Change in Lumbar Spine BMD From Start of Trial Period III Until End of Trial Period III. [Time Frame: 12 months]

Show Outcome Measure 1

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

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:** After publication of the results or 24 months after Clinical Trial Report has been finalised, whichever comes first, Nycomed acknowledge the Investigator's rights to publish results from this trial. Any such scientific paper, presentation, communication, or other information concerning the investigation described in this protocol, must be submitted to Nycomed prior to submission for publication/presentation for review. Review comments will be given within a month from receipt of the manuscript.

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Study First Received:	August 9, 2006
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Health Authority:	France: Ministry of Health Germany: Federal Institute for Drugs and Medical Devices Greece: Ministry of Health and Welfare Italy: The Italian Medicines Agency Spain: Spanish Agency of Medicines Sweden: Medical Products Agency Switzerland: Swissmedic United Kingdom: Medicines and Healthcare Products Regulatory Agency

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