# Effect of Full Length Parathyroid Hormone, PTH(1-84) or Strontium Ranelate on Bone Markers in Postmenopausal Women With Primary Osteoporosis (FP-006-IM)

**This study has been completed.**

**Sponsor:**
Nycomed

**Information provided by:**
Nycomed

**ClinicalTrials.gov Identifier:**
NCT00479037

First received: May 23, 2007
Last updated: May 4, 2012
Last verified: May 2012
History of Changes



Results First Received: March 31, 2011

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study;<br>Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment |
| **Condition:** | Osteoporosis |
| **Interventions:** | Drug: Full Length Parathyroid Hormone, PTH(1-84)<br>Drug: Strontium Ranelate |

## 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** |
|---|
| 82 subjects were randomized. Of these, one subject was randomized, but consent was withdrawn during the screening period; the subject did not receive any treatment. Therefore, the Intention to treat set (ITT) consisted of 81 subjects. |

**Reporting Groups**

| | **Description** |
|---|---|
| **PTH(1-84)** | Once daily subcutaneous injection |

| | |
|---|---|
| **Strontium Ranelate** | One sachet (2 g) per day, suspended in water |

**Participant Flow: Overall Study**

| | PTH(1-84) | Strontium Ranelate |
|---|---|---|
| **STARTED** | **41** | **40** |
| **COMPLETED** | **38** | **34** |
| **NOT COMPLETED** | **3** | **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 |
|---|---|
| **PTH(1-84)** | Once daily subcutaneous injection |
| **Strontium Ranelate** | One sachet (2 g) per day, suspended in water |
| **Total** | Total of all reporting groups |

**Baseline Measures**

| | PTH(1-84) | Strontium Ranelate | Total |
|---|---|---|---|
| **Number of Participants [units: participants]** | **41** | **40** | **81** |
| **Age [units: years] Mean (Standard Deviation)** | **64.0 (8.64)** | **64.9 (8.49)** | **64.4 (8.52)** |
| **Gender, Customized [units: participants]** | | | |
| **Female** | **41** | **40** | **81** |

## Outcome Measures

Show All Outcome Measures

1. Primary: Percentage Change in the Bone Formation Marker N-terminal Propeptides of Human Procollagen Type I (P1NP) From Baseline to End of Trial [ Time Frame: Baseline and 24 weeks of treatment ]

**Show Outcome Measure 1**

2. Primary: Percentage Change in the Bone Formation Marker Bone Specific Alkaline Phosphatase (BSAP) From Baseline to End of Trial [ Time Frame: Baseline and 24 weeks of treatment ]

**Show Outcome Measure 2**

3. Secondary: Percentage Change in the Bone Resorption Marker C-Telopeptide Cross-links (CTX) From Baseline to End of Trial [ Time

Frame: Baseline and 24 weeks of treatment ]

Show Outcome Measure 3

## 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** |
|---|
| A limitation of the trial was the open label design, however this is not considered to affect the primary or secondary outcome of the trial. |

## More Information

Hide More Information

**Certain Agreements:**

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|---|
| 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:<br>☐ 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.<br>☐ 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.<br>Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.<br>☑ **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. |

**Results Point of Contact:**

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Responsible Party: Nycomed
ClinicalTrials.gov Identifier: NCT00479037 History of Changes
Other Study ID Numbers: **FP-006-IM**
2006-006065-16

| | |
|---|---|
| Study First Received: | May 23, 2007 |
| Results First Received: | March 31, 2011 |
| Last Updated: | May 4, 2012 |
| Health Authority: | Austria: Ethikkommission<br>Spain: Spanish Agency of Medicines |

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