

A study to compare zoledronic acid and calcium and vitamin D, with placebo (dummy) and calcium and vitamin D, on the frequency of hip fractures and of new spinal fractures in post-menopausal women with osteoporosis

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/07/2014	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number**ClinicalTrials.gov number**

NCT00049829

Secondary identifying numbers

N0059115932

Study information

Scientific Title**Study objectives**

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

For the UK part of the trial, approved by North Sheffield Research Ethics Committee, reference NS02 1 1247, date of favourable opinion 21/03/02.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet**Health condition(s) or problem(s) studied**

Musculoskeletal Diseases: Osteoporosis

Interventions

Compare zoledronic acid and calcium and vitamin D, with placebo (dummy) and calcium and vitamin D.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Zoledronic acid, calcium, vitamin D

Primary outcome measure

Added 31 July 2008:

1. To assess the incidence of hip fractures in all patients treated with zoledronic acid compared to patients in the placebo group at 3 years
2. To assess the incidence of new vertebral fractures in patients treated with zoledronate acid compared to patients taking placebo at 3 years among patients not taking concomitant therapy for osteoporosis at baseline (stratum 1)

Secondary outcome measures

Added 31 July 2008:

1. Percent change in hip BMD as measured by DXA over 3 years
2. Proportion of patients in stratum 1 with new and/or worsening vertebral fractures at 1 year
3. Incidence of all clinical fractures in stratum 1 and 2 over 3 years

Overall study start date

01/07/2002

Completion date

30/06/2003

Eligibility

Key inclusion criteria

Post-menopausal women with osteoporosis.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

7,400 worldwide

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/07/2002

Date of final enrolment

30/06/2003

Locations

Countries of recruitment

England

Germany

United Kingdom

United States of America

Study participating centre

Metabolic Bone Centre

Sheffield

United Kingdom

S5 7AU

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Industry

Funder Name

Sheffield Teaching Hospitals (UK)

Funder Name

Novartis

Alternative Name(s)

Novartis AG, Novartis International AG

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/05/2007		Yes	No