ISRCTN16703536 https://doi.org/10.1186/ISRCTN16703536

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

Registration date
12/09/2003

Overall study status
Completed

Last Edited
11/07/2014

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00049829

Protocol serial number
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

Study type(s)
Not Specified

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(s)
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 vertebal fractures in patients treated with zolendronate acid compared to patients taking placebo at 3 years among patients not taking concomitant therapy for osteoporosis at baseline (stratum 1)

Key secondary outcome(s))
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

Completion date
30/06/2003

Eligibility

Key inclusion criteria
Post-menopausal women with osteoporosis.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

Germany

United States of America

Study participating centre
Metabolic Bone Centre
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
Department of Health (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

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