ISRCTN85429598 https://doi.org/10.1186/ISRCTN85429598

Effect of simvastatin on bone markers in osteopenic women: a placebo-controlled, dose-ranging trial

Submission date
26/02/2002

Recruitment status
No longer recruiting

Registration date
26/02/2002

Overall study status
Completed

Last Edited
06/09/2007

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Osteopenia

Interventions
1. Placebo once a day, at bedtime (qhs)
2. Simvastatin 20 mg qhs
3. Simvastatin 40 mg qhs

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Simvastatin

Primary outcome measure

Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2001

Completion date
01/05/2001

Eligibility

Key inclusion criteria
1. Women with osteopenia
2. Not taking oestrogen
3. Selective oestrogen receptor modulators
4. Bisphosphonates
5. Calcitonin
6. 3-hydroxy-3-methylglutaryl coenzyme A (HMG-coA) reductase inhibitors

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
24

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/02/2001

Date of final enrolment
01/05/2001

Locations

Countries of recruitment
United States of America

Study participating centre

George Washington University
Washington DC
United States of America
20037

Sponsor information

Organisation
George Washington University (USA)

Sponsor details
2150 Pennsylvania Ave NW
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United States of America
20037

Sponsor type
University/education

ROR
https://ror.org/00y4zzh67

Funder(s)

Funder type
Industry

Funder Name
Merck & Co. Inc. (USA) - unrestricted grant

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	01/01/2002		Yes	No