ISRCTN44380631 https://doi.org/10.1186/ISRCTN44380631

A pilot study to examine the effect of vitamin C on bone turnover and antioxidant levels in postmenopausal women with low bone density.

Submission date 30/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Stopped	
Last Edited 16/12/2010	**Condition category** Musculoskeletal Diseases	

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
N0112150254

Study information

Scientific Title

Study objectives
Does Vitamin C (a natural antioxidant) reduces bone turnover in women with postmenopausal osteoporosis?

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Osteoporosis

Interventions
Open label, randomised Study

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Changes in biochemical markers and antioxidant levels from baseline to end of study in vitamin C group. Group compared to controls

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/11/2004

Completion date
01/11/2005

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
Postmenopausal women with low bone density. Consenting healthy postmenopausel women with low bone density; osteopenia (Tscore<-1.0) as defined by the WHO 1994.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
On treatment for osteroporosis or taking any bone active drugs (e.g. oestrogens, steroids, vitamin D) or known to be suffering from diseases which can affect the skeleton such as renal or liver failure, malabsorption, thyrotoxicosis).

Date of first enrolment
01/11/2004

Date of final enrolment
01/11/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Epsom and St Helier NHS Trust
Carshalton
United Kingdom
SM5 1AA

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Epsom and St Helier University Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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