

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 16/12/2010	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Osteoporosis

Interventions

Open label, randomised Study

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

Not provided at time of registration

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 postmenopausal women with low bone density; osteopenia (Tscore<-1.0) as defined by the WHO 1994.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

On treatment for osteoporosis 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**

United Kingdom

England

Study participating centre

Epsom and St Helier NHS Trust

Carshalton

United Kingdom

SM5 1AA

Sponsor information**Organisation**

Department of Health

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

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration