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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

Contact name
Dr Sanjeev Patel

Contact details
Epsom and St Helier NHS Trust
Department of Rheumatology
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

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 postmenopausel 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 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
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