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A pilot randomised controlled trial to determine if vitamin D treatment will result in greater bone mass acquisition in pubertal girls

Submission date	Recruitment status	[_] Prospectively registered
28/09/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/10/2011	Nutritional, Metabolic, Endocrine	

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

N0453182967

Study information

Scientific Title

Study objectives
Does vitamin D status in young girls influence the accelerated bone growth that normally occurs around puberty and will supplementation with vitamin D to pubertal girls who have vitamin D deficiency lead to increased bone accrual in comparison to their placebo treated controls?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot randomised controlled study

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
Nutritional, Metabolic, Endocrine: Supplements

Interventions
The DXA and pQCT scans will be analysed by Dr Ward and Professor Adams who will be blinded as to the subject's study grouping. The primary muscle strength (JM force and power) and bone (TBBMC&D & radial BMC&D) outcome measures will be analysed after controlling for baseline measures, anthropometric variables, baseline 25(OH)D concentration, calcium intake and physical activity using appropriate analysis of covariance models. Descriptive and exploratory statistics will be used for the secondary outcomes, but these will be treated as exploratory. The correlation between Vitamin D status and serum ferritin concentrations will be determined using ANCOVA to adjust for treatment and other relevant variables.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin D

Primary outcome measure
The primary outcome measures for the study are the difference in bone mineral content and density over a 12 month period.

Secondary outcome measures
Not provided at time of registration

Overall study start date
12/06/2006

Completion date
30/08/2007

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Child

Sex
Female

Target number of participants
20 controls and 20 supplemented

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
12/06/2006

Date of final enrolment
30/08/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
SMH Central Manchester & Manchester Children's University Hospitals
Manchester
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M13 0JH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, 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
Government

Funder Name
Central Manchester and Manchester Children's 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2010		Yes	No