

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

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/10/2011	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

United Kingdom

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

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+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