ISRCTN72827849 https://doi.org/10.1186/ISRCTN72827849

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

Contact name
Dr M Z Mughal

Contact details
SMH Central Manchester & Manchester Children's University Hospitals
St Mary's Hospital for Women & Children
Oxford Road
Manchester
United Kingdom
M13 0JH
+44 0161 276 6501
zulf.mughal@cmmc.nhs.uk

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Pilot randomised controlled study

Study type(s)
Treatment

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

Key secondary outcome(s)
Not provided at time of registration

Completion date
30/08/2007

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
Female

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
United Kingdom

England

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

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

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