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

## Study design
Pilot randomised controlled study

## Primary study design
Interventional

## 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**

# 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 |