# 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	<ul><li>Prospectively registered</li></ul>		
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

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#### Contact details

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## 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

# 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