

# Calcium supplementation and weight-bearing physical activity: do they have a combined effect on the bone mineral density of pre-pubertal children?

<b>Submission date</b> 01/03/2001	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/03/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/01/2010	<b>Condition category</b> 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

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

AP0782

# Study information

## Scientific Title

A double blind, randomised controlled trial of the effects of calcium supplementation on bone density, geometry and strength in pre-pubertal gymnasts and healthy controls

## Study objectives

To investigate whether there is a differential response to calcium supplementation in elite gymnasts and school children controls.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Added 25/01/2010:

1. Central Manchester Research Ethics Committee approved on the 1st August 2000 (ref: CEN/00/44). South Manchester Ethics Board also gave approval on the 1st February 2001 under reciprocal arrangements with Central Manchester Research Ethics Committee which used to be in place in Manchester.
2. Stockport Research Ethics Committee approved on the 3rd July 2000 (ref: Min No 1875)
3. Liverpool Childrens Research Ethics Committee approved on the 3rd January 2002 (ref: 01/27/E)

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Calcium supplementation and bone mineral density

## Interventions

Gymnasts who participate in greater than 6 hours high intensity gymnastics a week. Sedentary children who participate in less than 2 hours high intensity weight bearing exercise per week.

**Intervention Type**

Supplement

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Calcium supplementation

**Primary outcome measure**

Increase in cortical and trabecular volumetric bone mineral density (vBMD) at the radius and tibia, assessed using peripheral quantitative computed tomography (pQCT).

Added 25/01/2010:

All outcomes were measured at baseline and 12 months after completing 12 months supplementation.

**Secondary outcome measures**

Changes in:

1. Bone geometry at the radius and tibia
2. Lumbar spine
3. Whole body measurements

Assessed using peripheral quantitative computed tomography (pQCT) (distal and diaphyseal radius and tibia) and dual energy X-ray absorptiometry (DXA) (lumbar spine and whole body).

Added 25/01/2010:

All outcomes were measured at baseline and 12 months after completing 12 months supplementation.

**Overall study start date**

01/01/2002

**Completion date**

01/01/2006

**Eligibility****Key inclusion criteria**

1. Pre-pubertal children aged 5 - 14 years, either sex
2. Signed parental or guardian consent received
3. Agreement to participate by the child

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

5 Years

**Upper age limit**

14 Years

**Sex**

Both

**Target number of participants**

86

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/01/2002

**Date of final enrolment**

01/01/2006

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Saint Mary's Hospital**

Manchester

United Kingdom

M13 0JH

**Sponsor information****Organisation**

Action Medical Research (UK)

**Sponsor details**

Vincent House

Horsham West Sussex

United Kingdom  
RH12 2DP

**Sponsor type**  
Charity

**Website**  
<http://www.action.org.uk/>

**ROR**  
<https://ror.org/01wcqa315>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
Action Medical Research (UK)

**Alternative Name(s)**  
actionmedres, action medical research for children, AMR

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Trusts, charities, foundations (both public and private)

**Location**  
United Kingdom

## **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?
<a href="#">Results article</a>	results	01/10/2007		Yes	No