ISRCTN84437785 https://doi.org/10.1186/ISRCTN84437785

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

Submission date	Recruitment status	[X] Prospectively registered
01/03/2001	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/03/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/01/2010	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr MZ Mughal

Contact details
Saint Mary's Hospital
Hathersage Road
Manchester
United Kingdom
M13 0JH
+44 (0)161 276 6501
zulf.mughal@man.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
14 years

Sex
All

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
United Kingdom

England

Study participating centre
Saint Mary's Hospital
Manchester
United Kingdom
M13 0JH

Sponsor information

Organisation
Action Medical Research (UK)

ROR
https://ror.org/01wcqa315

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research (UK)

Alternative Name(s)
action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2007		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes