ISRCTN90325334 https://doi.org/10.1186/ISRCTN90325334

A randomised controlled pilot study of weight-bearing standing programmes on bone mineral density in non-ambulant cerebral palsy children.

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/12/2009	Nervous System Diseases	

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
PCD2/A1/306

Study information

Scientific Title

Study objectives
The overall objective of this randomised pilot intervention study is to determine whether participation in a weight-bearing standing programme (approximately 50% increase in vertical or prone standing for one year) will lead to an improvement in volumetric bone mineral density of non-ambulant children with cerebral palsy.

Please note that as of 26/11/09 this record has been updated. All updates can be found in the relevant field with the above update date. Updated information was taken from 2004 publication (link below).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cerebral palsy

Interventions
Added 26/11/09
A heterogeneous group of 26 pre-pubertal children with CP (14 boys, 12 girls; age 4.3-10.8 years) participated in this randomised controlled trial. Subjects were matched into pairs using baseline vertebral vTBMD standard deviation scores. Children within the pairs were randomly allocated to either intervention (50% increase in the regular standing duration) or control (no increase in the regular standing duration) groups. Pre- and post-trial vertebral and proximal tibial vTBMD was measured by quantitative computed tomography (QCT)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in volumetric bone mineral density

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/1997

Completion date
31/10/2001

Eligibility

Key inclusion criteria
Non-ambulant cerebral palsy children who are able to weight-bear in a standing frame.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
26

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/11/1997

Date of final enrolment
31/10/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Paediactrics
Manchester
United Kingdom
M13 0JH

Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS National Physical and Complex Disabilities Programme (UK)

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?
Results article	results	01/02/2004		Yes	No