

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

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/12/2009	Condition category Nervous System Diseases	<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

Contact name

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Contact details

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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 Paediatrics
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