ISRCTN45840554 https://doi.org/10.1186/ISRCTN45840554

Osteopathy for children with Cerebral Palsy

Submission date	Recruitment status	[_] Prospectively registered
29/01/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/07/2011	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.pms.ac.uk/ocp/

Contact information

Type(s)
Scientific

Contact name
Prof Stuart Logan

Contact details
Peninsula College of Medicine and Dentistry
St Luke's Campus
Exeter
United Kingdom
EX1 2LU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
609136

Study information

Scientific Title
Osteopathy for children with Cerebral Palsy: a randomised controlled trial of the effects of osteopathy on the health and well being of children with cerebral palsy

Acronym
OCP Trial

Study objectives
In children aged 5 - 12 years of age with a diagnosis of cerebral palsy does osteopathy, compared to treatment as usual, produce improved motor function, improved quality of life, improved sleep or a reduction in fits?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southwest Research Ethics Committee approved 23rd February 2006 (ref: 06/MRE06/1)

Study design
Multicentre randomised controlled single-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Cerebral palsy

Interventions
Intervention group: six sessions of between 30 - 45 minutes duration of osteopathic treatment administered by General Osteopathic Council registered osteopaths over a six month period
Control group: waiting list control receives no treatment

Participants in both arms were in the trial for a total of six months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Gross Motor Function Measure assessed by a physiotherapist at 6 months, blinded to the child s allocation group
2. Child Health Questionnaire at baseline, 10 weeks and 6 months (please note that due to an update to this record on 03/02/2010, this outcome was upgraded from a secondary outcome to a primary outcome)

Secondary outcome measures
1. Paediatric Pain Profile at baseline, 10 weeks and 6 months
2. 36-item Short Form Health Survey (SF36) at at baseline, 10 weeks and 6 months
3. Sleep and Fit Diary at at baseline, 10 weeks and 6 months
4. Child Self-Report Pain Measure at at baseline, 10 weeks and 6 months
5. General Global Assessment of Health at 10 weeks and 6 months

Overall study start date
01/04/2006

Completion date
30/09/2008

Eligibility

Key inclusion criteria
1. Children with moderate to severe cerebral palsy classified as categories 2 - 5 of the Gross Motor Function Classification System
2. Aged 5 - 12 years, either sex
3. Live in study area, i.e. Devon or Greater London
4. At least one English speaking and literate parent
5. Must live at home with their parents/carers

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Classified as category 1 of the Gross Motor Function Classification System
2. Those who have had osteopathy within the previous year
3. Those who live in residential school

Date of first enrolment
01/04/2006

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Peninsula College of Medicine and Dentistry
Exeter
United Kingdom
EX1 2LU

Sponsor information

Organisation
Royal Devon and Exeter NHS Foundation Trust (UK)

Sponsor details
Royal Devon and Exeter Hospital (Wonford)
Barrack Road
Exeter
England
United Kingdom
EX2 5DW

Sponsor type
Hospital/treatment centre

Website
http://www.rdehospital.nhs.uk/

ROR
https://ror.org/03085z545

Funder(s)

Funder type
Charity

Funder Name
The Cerebra Foundation (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	01/06/2011		Yes	No