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Therapeutic effects of an advanced hippotherapy simulator in children with cerebral palsy

Submission date
19/02/2009

Recruitment status
No longer recruiting

Registration date
27/02/2009

Overall study status
Completed

Last Edited
20/07/2010

Condition category
Nervous System Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
N/A

Study information

Scientific Title
Study of the therapeutic effects of an advanced hippotherapy simulator in children with cerebral palsy: a randomised controlled trial

Study objectives
To analyse the therapeutic effects or the contraindications of the use of a commercial hippotherapy simulator on several important factors relating to children with cerebral palsy (CP) such as their motor development, balance control in the sitting posture, hip abduction range of motion and electromyographic (EMG) activity of adductor musculature.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee (CEIC Aragón) gave approval on the 6th June 2008 (ref: CP04/06/08)

Study design
Randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
The patients were classified into five levels according to the Gross Motor Function Classification System and subsequently randomly divided into two treatment groups:
1. Treatment Group with hippotherapy simulator (maintaining sitting posture, with legs in abduction and rhythmic movement of the simulator)
2. Treatment Group maintaining sitting posture, with legs in abduction and without rhythmic movement of the simulator

The randomising will be centralised and generated by computer to ensure a similar distribution of the possible confusion variables in both groups. The assignation sequence will be hidden. In cases where tutors or children do not wish to participate, their reasons will be recorded.

The independent variable in this study is the assigned therapeutic modality (treatment with hippotherapy simulator, or maintenance of sitting posture with legs in abduction but without rhythmic movement of the emulator). Each child will receive 10 treatment sessions. There will be one session a week of 15 minutes. The children not included in the simulator group are offered 10 treatment sessions with the simulator after the study has been completed. The dependent variables are:
1. Sitting balance
2. Measurement of hip abduction range of motion
3. Electromyographic activity in adductors
4. Gross motor function

Follow-up will continue until three months post-treatment completion.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Sitting balance:
1. Measurement of hip abduction range of motion, measured using an electronic inclinometer and traditional goniometer
2. Electromyographic activity in adductors, measured using surface electromyography (EMG)
3. Gross motor function, measured with the Gross Motor Function Measure (GMFM) and Sitting Assessment Scale (SAS)

Secondary outcome measures
Satisfaction of participants, measured using a 0 - 10 scale.

Overall study start date
01/10/2008

Completion date
01/10/2009

Eligibility

Key inclusion criteria
Children between 4 and 18 years old (either sex) with CP, who attend schools run by the Education Department of the Government of Aragon (Spain) and whose tutors have signed an informed consent form.

Participant type(s)
Patient

Age group

Child

Lower age limit
4 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
37

Key exclusion criteria
1. Children who have undergone selective dorsal rhizotomy
2. Acute convulsions not controlled by medication
3. Allergy to electrode adhesives
4. Visual impairment not corrected with glasses
5. Those circumstances or associated illnesses that in the judgment of the researcher might interfere with the results or be detrimental to the children
6. Inability to attend intervention sessions or refusal to participate

Date of first enrolment
01/10/2008

Date of final enrolment
01/10/2009

Locations

Countries of recruitment
Spain

Study participating centre
C/ Belle Epoque 27 Local
Zaragoza
Spain
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Sponsor information

Organisation
Regional Government of Aragon (Spain)

Sponsor details
Department of Research, Innovation and Development
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Sponsor type
Government

ROR
https://ror.org/0425pg203

Funder(s)

Funder type
Government

Funder Name
Regional Government of Aragon (Spain) - Department of Research, Innovation and Development (ref: PM059/2007)

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?
Protocol article	protocol	16/04/2010		Yes	No