

Asymmetry in infancy - the effect of pediatric physical therapy on the course of positional preference, deformational plagiocephaly and subsequent developmental delay

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/08/2008	Condition category Other	<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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR440

Study information

Scientific Title

Asymmetry in infancy - a prospective, randomised trial: the effect of pediatric physical therapy on the course of postional preference, deformational plagiocephaly and subsequent developmental delay, in children of 6 weeks to 24 months of age, measured with plagiocephalometry, range of motion tests and motor assessment

Study objectives

Pediatric physical therapy is effective in asymmetry in infancy, especially to positional preference, deformational plagiocephaly and natural course of asymmetrical motor development, established by plagiocephalometry, range of motion tests and motor assessment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local ethics committee

Study design

Randomised, single blinded, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

No condition, healthy person

Interventions

Study population:

Group 1: Positional preference (+/- deformational plagiocephaly) with pediatric physical therapy

Group 2: Positional preference (+/- deformational plagiocephaly) without pediatric physical therapy

Group 3: Deformational plagiocephaly without positional preference

Group 4: No positional preference and/or deformational plagiocephaly

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Parameters:

1. Shape of the head established by the features and values of plagiocephalometry
2. Active and passive range of motion measurements of the cervical column
3. Motor development by the Alberta Infant Motor Scale and the Bailey Scales of Infant Development second edition

All outcome parameters will be established at 4 investigation moments: T0 to T3

T0 = 6-8 weeks

T1 = 6 months

T2 = 12 months

T3 = 24 months

Secondary outcome measures

Answers to the questionnaires to investigate the experiences of parents of all participating children

Overall study start date

22/01/2005

Completion date

01/10/2007

Eligibility**Key inclusion criteria**

1. Healthy infants of 6 to 8 weeks of age, born at or after a gestational age of 36 weeks or more, without dysmorphisms or syndromatic symptoms
2. With or without positional preference of the head and with or without deformational plagiocephaly
3. Positional preference and deformational plagiocephaly are based on positional torticollis

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Weeks

Upper age limit

8 Weeks

Sex

Both

Target number of participants

385

Key exclusion criteria

1. Positional preference caused by pathology, for example congenital muscular torticollis, structural scoliosis, osseal disorders, cerebral palsy
2. Dysmorphism
3. Syndromes
4. Synostotic plagiocephaly (craniosynostosis)

Date of first enrolment

22/01/2005

Date of final enrolment

01/10/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

Bernhoven Hospital Veghel

Veghel

Netherlands

5460 DA

Sponsor information**Organisation**

Bernhoven Hospital Veghel (The Netherlands)

Sponsor details

P.O. Box 10.000

Veghel

Netherlands

5460 DA

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/05b5x0e19>

Funder(s)

Funder type

Research organisation

Funder Name

The Nuts-Ohra Foundation (Stichting Nuts Ohra [SNO]) (The Netherlands)

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	01/08/2008		Yes	No