

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	☐ Prospectively registered ☐ Protocol
Registration date 27/01/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/08/2008	Condition category Other	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised, single blinded, active controlled, parallel group trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Weeks

Upper age limit

8 Weeks

Sex

All

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)

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

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?
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[Results article](#)

Results

01/08/2008

Yes

No