

Asymmetry in Infancy

The effect of pediatric physical therapy on the course of positional preference, deformational plagiocephaly and subsequent developmental delay.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20651

Bron

Nationaal Trial Register

Verkorte titel

N/A

Aandoening

The children are born at the Bernhoven Hospital at Veghel, The Netherlands. The effects of the patients and controls are evaluated at the outpatient Department of the Bernhoven Hospital at veghel, The Netherlands

Ondersteuning

Primaire sponsor: Bernhoven Hospital, Veghel
P.O.Box 10.000
5460 DA Veghel
The Netherlands

Telephone: +31-413-381911

Overige ondersteuning: Stichting Nuts Ohra

P.O. Box 229

1000 AE Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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 every of 4 investigation moments: T0 to T3.

T0 = 6-8 weeks

T1 = 6 months

T2 = 12 months

T3 = 24 months.

Toelichting onderzoek

Achtergrond van het onderzoek

This trial started with a cohort study of 400 newborns. At the age of 6-8 weeks the state of asymmetry of infancy is achieved by several parameters. The randomised controlled trial include four groups of children.

Because I am not working in an Academic Centre and my long holiday, I heard the ultimate date to announce this trail very late. I hope it will be possible to register this trial, which was started before July 2005.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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 postional torticollis.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	22-01-2005
Aantal proefpersonen:	385

Type:

Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:

02-10-2005

Soort:

Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL400
NTR-old	NTR440
Ander register	: N/A
ISRCTN	ISRCTN84132771

Resultaten

Samenvatting resultaten

1. Van Vlimmeren LA, Helders PJ, Van Adrichem LN, et al. Diagnostic strategies for the evaluation of asymmetry in infancy; A Review. Eur J Pediatr. 2004;163:185-191.

2. Van Vlimmeren LA, Helders PJ, Van Adrichem LN, Engelbert RHH. Torticollis and plagiocephaly in infancy: Therapeutic strategies - A Review. Ped Rehab 2005. In press.

3. Van Vlimmeren LA, Takken T, Van Adrichem LNA, Van der Graaf Y, Helders PJM, Engelbert RHH. Plagiocephalometry: a non-invasive method to quantify asymmetry of the skull - a reliability study -

Eur J Pediatr 2005. In press.