Deformational plagiocephaly: effects and costs of helmet treatment and a wait-and-see regimen

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The research question of the main study is: What are the short- and long-term effects and costs of helmet treatmentcompared to a wait-and-see regimen for a period of 6 months on skull asymmetry in children withmoderate to severe DP.The objective of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON35689

Source
ToetsingOnline

Brief title
Treatment of plagiocephaly

Condition

- Bone disorders (excl congenital and fractures)

Synonym
head molding, plagiocephaly

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: deformational plagiocephaly, helmet treatment, orthotic device, randomised controlled trial

Outcome measures

Primary outcome

Primary outcome is the (a)symmetry of the skull at 8, 12, and 24 months,

measured

by PCM.

Secondary outcome

Secondary outcome of the main study:

- subjective outcome score;

- (psycho)motor development;

- quality of life;

- parental attitudes;

- parental anxiety level and parental concerns;

- satisfaction with the treatment.

Secondary outcome of the ancillary methods study:

- actual preference for treatment (randomisation, helmet, wait-and-see);

- Decisional Conflict Scale;

- stated preference for treatment.

Study description

Background summary

Deformational plagiocephaly/brachycephaly (together *DP*) refers to a condition in which the infant*s
head - and possibly the face - are deformed as a result of prenatal and/or postnatal external forces to
the malleable and growing cranium. This often leads to an asymmetric cranium, ear misalignment and
facial asymmetry. When only the occiput is flattened (symmetrically), the condition is called
brachycephaly. The number of children with DP treated with a helmet has risen dramatically in the past
decade. The effectiveness of treatment has not been illustrated.

Study objective

The research question of the main study is: What are the short- and long-term effects and costs of helmet treatment
compared to a wait-and-see regimen for a period of 6 months on skull asymmetry in children with
moderate to severe DP.

The objective of the ancillary methods study is to assess preferences of parents and professionals for treatment
characteristics and to study the relation with actual treatment choice, clinical outcome and treatment satisfaction.

Study design

A randomised controlled trial into the effectiveness of helmet treatment, nested in a follow-up study.

Intervention

Included children will be randomly assigned to either helmet treatment or a wait-and-see
regimen, both for a period of 6 months.

Study burden and risks

- The child and his parents are not exposed to any specific risks.
- Helmet treatment has almost become regular treatment, although effectiveness has not been illustrated in RCT's. Therefore the burden for patients is not different from the current situation.
- At het age of 2-4, 5, 8, 12 and 24 months, the child is examined including plagiocefalometry (PCM). These consultations will take about 30 minutes (PCM, questionnaires). At the age of 2-4, 5, 8 and 12 months, the measurements are linked to regular consultations of the pediatric physiotherapist and cost

relatively little extra time of parents. Furthermore, the consultations take place at the practice location of the pediatric physiotherapist, close to the residence of the parents.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants in the age of 5-6 months with the following PCM inclusion criteria: plagiocephaly 108% <= ODDI <= 113, brachycephaly 95 <= CPI <= 104%, mixed forms according to adjusted criteria for ODDI and CPI.

Exclusion criteria

Premature children (< 37 weeks), children with congenital muscular torticollis, synostotic plagiocephaly and/or dysmorphisms

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2009
Enrollment:	96
Type:	Actual

Medical products/devices used

Generic name:	Helmet;cranial orthotic device
Registration:	No

Ethics review

Approved WMO Date:	18-12-2008
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	23-06-2011
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ISRCTN	ISRCTN18473161
CCMO	NL24352.044.08