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

Submission date	Recruitment status	[X] Prospectively registered
19/09/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/06/2014	Musculoskeletal Diseases	

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
ZonMw nr 170992501

Study information

Scientific Title

Study objectives
In comparison with a wait-and-see regimen, redression helmet treatment in infants with deformational plagiocephaly (DP) is more effective, measured subjectively with a Satisfaction Outcome Score and objectively with plagiocephalometry.

An ancilliary study is also taking place with the following objective: what is the agreement between parental stated preferences for management of plagiocephaly (measured with conjoint analysis) and actual management preferences (helmet treatment, randomisation, wait and see)?

Thw hypothesis for this ancilliary study is that parental stated preferences predict parental actual decision making.

As of 31/01/2012, the anticipated end date of trial was updated from 31/12/2011 to 30/04/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 11/03/2009: Medical Ethics Committee gave approval on the 8th January 2009 (ref: NL24352.044.08)

Study design
Randomised controlled trial, nested in a follow-up study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Deformational plagiocephaly/brachycephaly

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

Intervention group:
Helmet treatment initiated at the age of 5 months and supervised by a physician in one of the two specialised centres. A custom-made helmet is constructed by an orthotist and is made of mouldable plastic. The helmet is worn both day and night, for an average of four to six months.

Wait-and-see group:
Recovery of the deformation of the head is awaited by allowing spontaneous growth of the skull. Preceding physiotherapy will be discontinued.

The paediatric physiotherapist will perform the follow-up measurements in both the intervention and the wait-and-see group at the age of 8, 12, and 24 months (and 48 months, beyond the scope of this study). During these measuring moments, advice is given on positioning and handling of the child. This advice is also given by YHC physicians and nurses as part of usual care to all infants.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
(A)symmetry of the skull at 8, 12, and 24 months, measured by plagiocephalometry (PCM).

Secondary outcome measures
Main study:
1. Subjective outcome score (at 5, 12, 24 months)
2. (Psycho)motor development (at 5, 12 and 24 months)
3. Quality of life (at 2 years)
4. Parental attitudes (at 5, 12 and 24 months)
5. Parental anxiety level and parental concerns (at 5, 12 and 24 months)
6. Satisfaction with the treatment (at 12 and 24 months)

Secondary outcome of the ancillary methods study:
1. Decisional conflict scale
2. Actual preference for treatment (helmet, wait-and-see, randomised controlled trial [RCT])
3. Stated preference for treatment

Overall study start date
01/01/2009

Completion date
30/04/2013

Eligibility

Key inclusion criteria
1. Children 5 months of age, either sex
2. Moderate to severe DP:
2.1. Plagiocephaly: 108% less than or equal to Oblique Diameter Difference Index (ODDI) less than or equal to 113%
2.2. Brachycephaly: 95% less than or equal to Cranial Proportional Index (CPI) less than or equal to 104%
2.3. Mixed forms according to adjusted criteria

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Months

Sex
Both

Target number of participants
96

Key exclusion criteria
1. Premature children
2. Children with congenital muscular torticollis
3. Synostosis
4. Dysmorphisms
5. Neurological dysfunctions

Date of first enrolment
01/01/2009

Date of final enrolment
30/04/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
University of Twente
Enschede
Netherlands
7500 AE

Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Sponsor details
Laan van Nieuw Oost Indië 334
P.O.Box 93245
The Hague
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2509 AE

Sponsor type
Research organisation

Website
http://www.zonmw.nl

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)
(ref: 80-82310-98-09091)

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	09/07/2012		Yes	No
Results article	results	01/05/2014		Yes	No