

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

Submission date 19/09/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 17/10/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/06/2014	Condition category Musculoskeletal Diseases	☐ 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
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 ancillary 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)?

The hypothesis for this ancillary 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 months

Sex

All

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)

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

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	01/05/2014		Yes	No
Protocol article	protocol	09/07/2012		Yes	No