

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

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/10/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/06/2014	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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

**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)?

The 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

Netherlands

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?
<a href="#">Protocol article</a>	protocol	09/07/2012		Yes	No
<a href="#">Results article</a>	results	01/05/2014		Yes	No