ISRCTN18473161 https://doi.org/10.1186/ISRCTN18473161

# 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

**Contact name**
Dr Magda M. Boere-Boonekamp

**Contact details**
University of Twente
Health Technology and Services Research
Drienerlolaan 5
P.O.Box 217
Enschede
Netherlands
7500 AE
+31 (0)53 4894483
M.M.Boere-Boonekamp@utwente.nl

## 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 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

## 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 |