Active Monitoring versus an Abduction Device for treatment of Infants with Centered Dysplastic Hips, a Comprehensive Cohort Study (TReatment with Active Monitoring (TRAM)-Trial)

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The aim of this study is to compare treatment with an abduction device to active monitoring of infants with centered dysplastic hips (Graf type IIa- or IIb or IIc) during the first year of life.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Interventional

Summary

ID

NL-OMON56369

Source
ToetsingOnline

Brief title
The TRAM-Trial: Treatment with Active Monitoring

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
abnormal hip development, hip dysplasia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: zonMW

Intervention

Keyword: -abduction device, -active monitoring, -dysplastic hip

Outcome measures

Primary outcome

active monitoring of infants with stable centered DDH (Graf type IIa-/IIb/IIc)

does not result in a lower proportion of infants with normal hips (success:

acetabular index lower than 25 degrees on radiograph) at the age of 12 months

compared to abduction treatment (a non-inferiority study).

Secondary outcome

- What is the difference in success rate between both study groups at the age

of 24 months?

- Do fewer complications occur when infants are treated with active monitoring

compared to treatment with a dynamic abduction device?

- What is the difference in time to Graf I?

- Which factors are associated with the outcome at 12 and 24 months?

- Are parents compliant to the abduction device?

- Is treatment with active monitoring cost effective to treatment with a

dynamic abduction device?

- What is the quality of life of the infants and of the parents?

- Is parent-satisfaction different between both treatment options?

Study description

Background summary

The diagnosis Developmental Dysplasia of the Hip (DDH) is used for a wide spectrum of growth disorders of neonatal and infant hips. The incidence of dysplastic hip joints in The Netherlands is 1-4% of the infants up to 6 months of age. Of these infants, the vast majority concerns stable, centered hips. Only 10% of all DDH patients have instable or dislocated hips.
Residual dysplasia can lead to deterioration of the hip joint causing chronic pain, degenerative hip disease and gait abnormalities later in life. Over treatment of patients with normalizing hips during growth is a burden for children, parents, and society and has a risk of introducing unnecessary complications.
Diagnosis and classification of DDH is done by ultrasound using the Graf method. Type 2 hips are stable but dysplastic. Type 3 and 4 hips are unstable or dislocated.
Current treatment of all types of DDH uses a dynamic abduction device (Pavlik harness). Treatment consists of centering the hip in the acetabulum and subsequently gaining pressure in the deepest part of the acetabulum in order to develop a sufficient bony and cartilaginous roof [6]. In dislocated hips this treatment is proven effective in multiple studies. However, evidence for treating centered, dysplastic hips (Graf type 2) is lacking. Natural history seems more favorable for these hips compared to treatment since the vast majority of centered hips tend to normalize during growth. Treatment does expose the infants to the risks of abduction treatment, mainly avascular necrosis (AVN) of the femoral head in 2-11% of the patients and (transient) femoral nerve palsy in 2.5% of the cases. Furthermore, treatment of infants of 3 months old often induces stress and dilemma*s in families. Daily activities, such as diaper changing, cleaning and carrying are more complex and the impact of abduction treatment at this age is a burden for the whole family. In addition, reducing unnecessary medical treatment will be cost-saving for society as a whole. Therefore, active monitoring might be a useful alternative in these infants with centered dysplastic hips. Active monitoring consists of ultrasound and physical examination in order to receive appropriate treatment if the hip deteriorates into a decentered hip.

Study objective

The aim of this study is to compare treatment with an abduction device to active monitoring of infants with centered dysplastic hips (Graf type IIa- or IIb or IIc) during the first year of life.

Study design

The present study compares the costs and effectiveness of two treatment options for infants with a stable, centered dysplastic hip, namely active monitoring or the use of a dynamic abduction device, following a comprehensive cohort design (CCD). The study is an open label study since blinding is not possible for the patients/parents as well as for the treating physician. All patients will be included after diagnosis at the outpatient clinic of the orthopedic department.

The CCD consists of a randomized controlled trial (RCT) and a parallel prospective cohort, each with two arms (abduction treatment and active monitoring; Figure 1). Primarily, parents/caregivers are asked to participate in the RCT. In the prospective cohort, infants are included whose parents/caregivers do not want their infant to be randomized to one of the RCT*s treatment arms (i.e., who prefer either the abduction treatment or active monitoring), but who are willing to participate in the study.

Treatment group assignment will take place at patient level. In case of randomization, stratification for type IIa-/IIb/IIc DDH and for center will be applied. In the parallel prospective cohort, parent/caregiver preference decides treatment group assignment.

Patients will be followed for 24 months.

Intervention

use of the Pavlik harness (abduction treatment)

Study burden and risks

Research suggests that active monitoring might be a good alternative for the treatment of patients with centered dysplastic hips. Patients will be monitored frequently and actively, in order to treat the hip in case of deterioration. Therefore, the risks of this study are comparable to the risks involved with standard treatment. No extra visits compared to regular care are necessary. For the infants there will be no extra burden compared to regular care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)

Inclusion criteria

- patients with Graf 2a- or 2b or 2c DDH
-10-20 weeks old
-good command of the dutch language of the parents
-parental informed consent

Exclusion criteria

-hip instability
-(suspicion of) syndromal disease
-prematurity (defined as a gestational age < 37 weeks)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-05-2022
Enrollment:	800
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	04-03-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	09-11-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	19-09-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	14-08-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	11-04-2025
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL75859.068.21
Other	NL9714