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

Gepubliceerd: 06-09-2021 Laatst bijgewerkt: 18-08-2022

We hypothesize that active monitoring of infants with stable centered DDH (Graf type 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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29596

Bron
NTR

Verkorte titel
TRAM-Trial

Aandoening

Stable centered Developmental Dysplasia of the Hip (DDH)

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Acetabular index at the age of 12 months

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Current treatment of all types of DDH in infants of 3-4 months old uses an 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. In dislocated hips this treatment is proven effective in multiple studies. However, evidence for treating centered dysplastic hips is lacking. Natural history seems more favorable for these hips compared to treatment since the vast majority of centered hips tends to normalize during growth. Furthermore, 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. Therefore, active monitoring, consisting of frequent ultrasound and physical examination, might be a useful alternative in these infants with centered dysplastic hips.

Objective: The primary objective is to assess whether active monitoring of infants with stable centered DDH (Graf type 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 objectives:
• 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 reach 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 design: This study will be an open-label multicentre RCT. Infants will be randomized, following the diagnosis of Graf type IIa-/IIb/IIc hip dysplasia in two groups:
1. Treatment with an abduction device (usual care)
2. Active monitoring
Patients will be followed up to 24 months of age.

Study population: In order to be eligible for participation in this study, a subject must meet all of the following criteria: Graf IIb or IIc DDH, diagnosed with ultrasound; Age 10-16 weeks; In case of a bilateral DDH, the hip with the worst Graf classification will be included (randomisation per infant); Good command of Dutch language of the parents; parental informed consent. Exclusion criteria are: Hip dislocation; Age <10 weeks or > 16 weeks; (Suspicion of) syndromal disease (e.g. arthrogryposis, cerebral palsy, Down syndrome); Prematurity (defined as a gestational age <37 weeks)

Intervention (if applicable): Patients will be randomized to usual care (abduction device) or active monitoring.

Main study parameters/endpoints:
Primary parameter:
Acetabular index at the age of 12 months
Secondary parameters:
Acetabular index at the age of 24 months
Complications
Time to achieve a normal hip
Factors associated with outcome at 12 and 24 months
Compliance of the parents
Costs, cost-effectiveness and budget impact
Health-related quality of life of infants and parents
Parent-satisfaction

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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. Every 6 months, parents have to answer several questions on costs, quality of life and satisfaction, which is extra to regular care. For the infants there will be no extra burden compared to regular care.

Doel van het onderzoek

We hypothesize that active monitoring of infants with stable centered DDH (Graf type 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).

Onderzoeksopzet

- T1 (10-16 weeks): baseline characteristics; physical examination; ultrasound; quality of life of the infant; quality of life of the parents
- T2 (every 6 weeks): physical examination; ultrasound; compliance; complications
- T3 (every 6 months): parent satisfaction; quality of life of the infant; quality of life of the parents; cost questionnaire

- T4 (12 months): physical examination; complications; X-ray
- T5 (24 months): physical examination; complications; X-ray

Onderzoeksproduct en/of interventie

Active monitoring:
Active monitoring: patients will not receive an abduction device. Patients will receive ultrasound monitoring every 6 weeks and physical examination, until:
1. full recovery of the hip into Graf type I
2. a total period of 18 weeks
3. no improvement of alpha angle is seen on two consecutive ultrasounds
4. deterioration of the hip is seen at clinical examination or on ultrasound, or
5. inability to make an ultrasound because of progressive development of the ossific nucleus of the femoral head.
In case of 1 treatment will be discontinued, as maximal results are accomplished.
In case of 2,3, or 4, patients will receive treatment according to the standardized protocol for usual care.
In case of 5, follow-up will be continued by obtaining radiographs.
*Deterioration for Graf type 2C is defined as worsening or not improving into Graf 2B within 12 weeks.

Usual care: Patients will receive a dynamic abduction device (Pavlik harness). Treatment is commenced directly at diagnosis, using the Pavlik harness in 100 degrees of flexion of both hips and maximal comfortable abduction. Regular check-up after 1 and/or 2 weeks is advised at start of Pavlik treatment.
Patients will receive ultrasound monitoring every 6 weeks and physical examination.
The Pavlik harness will be continued until:
(1) full recovery of the hip into Graf type I,
(2) no improvement of alpha angle is seen on two consecutive ultrasounds
(3) deterioration of the hip is seen at clinical examination or on ultrasound
(4) the infant is too strong for the Pavlik harness
(5) inability to make an ultrasound because of progressive development of the ossific nucleus of the femoral head.
In case of (1) or (2) treatment with Pavlik will be discontinued, as maximal results are accomplished. There is no indication for weaning, Pavlik can be discontinued directly
In case of (3) patients will receive treatment according to the standardized protocol (figure 1, flowchart of the study).
In case of (4) abduction treatment will be continued using a static abduction device (e.g. CAMP device) until (1), (2) or (3) is accomplished.
In case of (5) follow-up will be continued by obtaining radiographs.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible for participation in this study, a subject must meet all of the following criteria:
Graf IIb or IIc DDH, diagnosed with ultrasound; Age 10-16 weeks; In case of a bilateral DDH, the hip with the worst Graf classification will be included; Good command of Dutch language of the parents; Parental informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study: Hip instability; Age <10 weeks or >16 weeks; (Suspicion of) syndromal disease (e.g. arthrogryposis, cerebral palsy, Down syndrome); Prematurity (defined as a gestational age <37 weeks).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9714
Ander register	METC azM/UM : METC 21-036

Resultaten

Samenvatting resultaten
N/A