The effect of Abduction therapy on stable developmental dysplasia of the hip (DDH) between the age of 3 and 6 months.

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The purpose of this study is to show no difference in the outcome with abduction treatment versus no treatment in stable hip dysplasia between the age of 3 and 6 months.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON36841

Source
ToetsingOnline

Brief title
Hip dysplasia and abduction treatment

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
DDH, Hip dysplasia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: abduction, hip dysplasia, RCT

Outcome measures

Primary outcome

US measurements after 3 months of supervised neglect or 3 motnhs of regular

Pavlik harness treatment.

Secondary outcome

Femoral head necrosis percentage in abduction treatment group (control group)

Study description

Background summary

DDH is treated at a young age to prevent hip dysplasia in adult life with a subsequent increased risk on arthrosis, pain and invalidity. This increased risk is documented in the literature (1,2,9). In the Netherlands, stable hip dysplasia (Graf 2b en 2 c) is treated as of 3 months of age. In many other European countries, stable DDH is treated as of the first month of age often in relation to the screening program of that country. The abduction treatment should improve the relationship between femoral head and acetabulum and increase the development of the acetabulum. However, the effect of abduction treatment is never proved in children of 3 months old with stable DDH.
The only study on the natural history of stable hip dysplasia has showed a surprisingly result (78% normalisation at the age of 18 years). RCT is abduction treatment below the age of 3 months has not showed any effect and the natural history shows normalisation in the majority of cases. The discussion on the indication of abduction treatment in children with stable DH remains because of the risk on avascular necrosis with subsequent growth disturbance of the femoral head.
Treatment and follow-up with ultrasound (US) or rontgenographs (X-rays) is done by medical specialists. Dor US or X-ray investigations, the classifications respectively according to Graf (tabel 1) and Tonnis (table 2) are used.

Classification Graf, Table 1
Type Graf Alpha / Beta angle age Classification
Ia *60 / *55 any age Normal
Ib *60 / >50 0-3 months(mos) Normal

IIa 50-60 / 55-70 * 3 mos Immature
IIb 50-60 / 55-70 > 3 mos Stable dysplasia
IIc 43-50 / 70-77 any age Severe dysplasia
D 43-50 / >77 any age Decentered
III <43 / >77 any age Subluxation
IV no angle/ >77 any age Dislocation

Alpha angle is the angle between the line along the bony part of the acetabulum and the reference line paralel to the lateral aspect of the os ilium. Beta angle is the angle between the line through the labrum (cartilage roof) and the bony rim (turning point concavity-convexity).

Classification Tõnnis en Brunken, Table 2

Grade I normal
Grade II mild pathology
Grade III severe pathology
Grade IV extreme pathology

age mean I II
III IV
3-4 mos 25 < 30 30-34 35-39 * 40
5-24 mos 20 < 25 25-29 30-34 * 35
2-3 years 18 < 23 23-27 28-32 * 33
3-7 years 15 < 20 20-24 25-29 * 30
7-14 years 10 < 15 15-19 20-24 * 25

The AC-angle is the angle between the line along the acetabulum and to a horizontal line through the centers of the triradiate cartilages on an AP X-ray of the pelvis. (Fig 2)

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Study objective

The purpose of this study is to show no difference in the outcome with abduction treatment versus no treatment in stable hip dysplasia between the age of 3 and 6 months.

Study design

Open prospective multi-center randomised trial. One half of the study group will have the regular treatment with the Pavlik harness, the other half will have supervised neglect. The choice of treatment for the individual child will be made with randomisation lists generated by the computer. We expect no relevant differences in sex after randomisation.
To maximize equality in group comparison, type IIb en type IIc will be randomised.

Patient numbers
In all 5 participating hospitals, patients will be included recording the inclusion criteria. Based on an estimated national incidence of 2% of hipsdysplasia type IIb en IIC, we expect to include 20 patients a year for each center.
After one year, the number of patients included should be 100.

Treatment in one half of the study group will consist of Pavlik harness according to standard treatment protocol, compared to supervised neglect in the other half of the study group.
The parents will be asked to register the contacts with the hospital.
US follow up will be after 6 weeks en 3 months.

In case of worsening of the type of dysplasia to Graf D after 6 weeks follow-up and in case of persisting DDH at 3 months follow-up, regular treatment will be started.
All children who have normal US after 3 months of follow-up will be considered as good and no treatment will be given at this point.
Further follow-up will be done by US at 6 months and an x-ray of the pelvis at 9 months follow-up.
complications will be registrated on a separate form.

Intervention

supervised neglect versus regular treatment with Pavlik harness

Study burden and risks

extension of period of abduction treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All children age 3 and 4 months with stable DDH (Graf IIb and IIc) who present at the different participating clinical centers.

Exclusion criteria

Children not in age category 3-4 months, Graf type I, D, III and IV.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-12-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	29-07-2008

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-08-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL24195.041.08