Guided growth of the proximal femur to prevent further;hip migration in cerebral palsy patients

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To determine whether guided growth of the proximal femur decreases the risk of further hip migration and need for further surgery in cerebral palsy patients.

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

Summary

ID

NL-OMON56489

Source
ToetsingOnline

Brief title
Guidance

Condition

- Joint disorders

Synonym
hip migration / dysplasia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: for Wis(h)dom foundation

Intervention

Keyword: cerebral palsy, children, guided growth, hip migration

Outcome measures

Primary outcome

Need for secondary (bony) surgery and/or progression to a migration percentage

of > 50%.

Secondary outcome

- Change in migration percentage

- Head shaft angle

- Complication rate

- Screw revision rate

- CP - child questionnaire

Study description

Background summary

In recent literature, the potential of guided growth of the proximal femur to modify hip growth in patients with cerebral palsy has been shown. Using medial hemi-epiphysiodesis of the proximal femur (TMH-PF) morphology of hips at risk of symptomatic (sub)luxation in cerebral palsy (CP) can be changed, aiming to reduce further hip migration and the need for more invasive surgical treatment modalities. Further research is necessary to assess if the results of TMH-PF in combination with adductor tenotomies are significantly better than the results of the current standard of care; adductor tenotomies alone.

Study objective

To determine whether guided growth of the proximal femur decreases the risk of further hip migration and need for further surgery in cerebral palsy patients.

Study design

Multicentre, randomized, controlled trial.

Intervention

The intervention group undergoes an adductor tenotomy combined with temporary medial hemi-epiphysiodese of the proximal femur. The control group undergoes an adductor tenotomy alone.

Study burden and risks

- Both groups of patients will undergo surgery in accordance with the current standard of care.
- Both groups will have the same clinic appointments, including physical examination and radiological follow-up, in accordance with the current standard of care.
- Patients will be asked to fill out a CP - child preoperatively as well as at the 6 week postoperative mark and at the 1 year postoperative appointment [7].
- The group of patients undergoing TMH-PF will have additional surgical risks: Risk of infection, the need for screw revision. However, they might also benefit from the advantages of this technique in the form of preventing secondary bony surgery.
- All patients will undergo a low-dose CT scan directly postoperatively, at 2 years postoperatively and at 5 years postoperatively to assess 3-dimensional morphological changes of the hip.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 40
Rotterdam 3015 GB
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 40
Rotterdam 3015 GB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Spastic CP
- GMFCS level IV-V
- Aged 2-8 years
- Abduction in flexion <= 40 degrees
- Migration percentage of 30-50%
- Head shaft angle > 145 degrees

Exclusion criteria

- Not fit for surgery
- History of bony hip surgery to the affected hip
- Severe acetabular dysplasia defined as a gothic arch, a incongruent joint or an acetabular index > 30 degrees, consistent with A2 and A3 acetabular deformity according to Robin and Graham

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:	Recruiting
Start date (anticipated):	06-04-2024
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO Date:	16-02-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-09-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL84133.078.24