# Long term follow-up after a Salter pelvic osteotomy.

Published: 20-07-2015 Last updated: 21-04-2024

- To determine the long-term results of Salter pelvic osteotomies.- To determine the differences in outcome between an open reduction at a relatively young age and an open reduction at the time of the pelvic osteotomy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational invasive

# Summary

### ID

NL-OMON41976

**Source** ToetsingOnline

**Brief title** Long term follow-up after a Salter pelvic osteotomy.

# Condition

- Musculoskeletal and connective tissue disorders congenital
- · Bone and joint therapeutic procedures

#### **Synonym** Congenital hip dysplasia, developmental hip dysplasia

#### **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud **Source(s) of monetary or material Support:** Eigen onderzoeksbudget van de afdeling orthopedie.

## Intervention

Keyword: Arthroplasty, Hip dysplasia, Long term, Pelvic osteotomy

## **Outcome measures**

#### **Primary outcome**

- VAS scores
- Range of motion
- Harris hip score
- Oxford hip questionnaire
- Merle d'Aubigne score
- Radiological presence of osteoarthritis
- Total hip arthroplasty

#### Secondary outcome

- Postoperative complications

# **Study description**

#### **Background summary**

The Salter pelvic osteotomy is a corrective osteotomy of the pelvis which is performed in children with hip dysplasia between the ages of 1,5 to 4 years. The UMCN has extensive experience with this procedure and we therefore have a vast number of patients that have had their hip dysplasia treated in this manner. This type of osteotomy, however, does not create a normal acetabulum and it is therefore not unthinkable that several patients do develop osteoarthritis of the hip at a relatively young age. Considering the impact of this procedure (both with regards to the operative impact as well as the postoperative treatment, which consist cast immobilisation for 6 weeks) it is important to know in which patients this procedure will be a success and which patients should be prepared for complications at a later age. Next to that, part of these patients underwent an open reduction as well as a pelvic osteotomy. As part of this open reduction, it was customary to resect the labrum in order to properly reduce the hip. Lately, however, the importance of the labrum in the development of the hip and preventing osteoarthritis has become more and more clear and we are therefore curious to see which number of these patients develop hip complaints after reaching skeletal maturity. In this total population, there is also a group of patients who have undergone an open reduction at a young age (under 1 year). In these patients, we are very curious to see what the long-term consequences are of this early open reduction and what the success rates are of Salter pelvic osteotomies.

#### **Study objective**

- To determine the long-term results of Salter pelvic osteotomies.

- To determine the differences in outcome between an open reduction at a relatively young age and an open reduction at the time of the pelvic osteotomy.

## Study design

The plan is to look up all 77 patients and call them in for one visit to the outpatient clinic. Before their visit they will be informed on the study through the included leaflets. During their visit the following information will be obtained;

- Physical examination; range of motion
- VAS painscore
- Harris hip score
- Oxford hip questionnaire
- Merle d'aubigne score
- Pelvic x-ray

For the patients, this amounts to a visit of 15-30 minutes in which they fill out the questionnaires, get the physical examination and have an x-ray taken. The radiological load is acceptable and amounts to a total of 0,31 mSvt. If a patient has a lot of discomfort or even impaired range of motion, a complete evaluation can be performed by one of the hospitals hip specialists (Dr. Scheurs or Dr. Rijnen) and further treatment can be initiated.

### Study burden and risks

- Visit to the outpatient clinic; not including travelling 15-30 minutes
- Physical examination
- Radiation: 0,21 mSvt; acceptable risk.

# Contacts

#### Public

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Elderly (65 years and older)

## **Inclusion criteria**

Healthy patients after a Salter pelvic osteotomy performed at our hospital who are now 16 or older.

## **Exclusion criteria**

- Patients with comorbidities influencing the outcome of hip dysplasia, such as Down's syndrome or cerebral palsy.

- Patients under 16 years old.

# Study design

# Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Prevention	

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2015
Enrollment:	77
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	20-07-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

# **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

ССМО

**ID** NL51879.091.14