Clinical and radiological results 10 years after a deepening trochleoplasty

Published: 05-10-2017
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To evaluate the radiological and clinical outcomes 10 years after a trochleoplasty. We are especially interested in the cartilage status and patellofemoral pain of the patients.

Ethical review	Approved WMO
Status	Completed
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON50571

Source
ToetsingOnline

Brief title
Long-term results trochleoplasty

Condition

- Bone and joint therapeutic procedures

Synonym
Trochleoplasty; Trochlear dysplasia

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: eigen middelen Sint Maartenskliniek

Intervention

Keyword: Cartilage damage, MRI, Osteoartritis, Trochleoplasty

Outcome measures

Primary outcome

The primary outcome is cartilage status determined on MRI and expressed by a semiquantative score for knee osteoarthritis (MOAKS score).

Secondary outcome

Secondary outcomes are clinical and radiological outcome in terms of pain and functioning measured by patient reported outcome measurements and patellofemoral osteoarthritis measured on conventional X-rays.

Study description

Background summary

Trochlear dysplasia is the most consistent anatomic factor present in patients with recurrent patellar dislocations. Due to the change in the trochlea during the trochleoplasty the patellofemoral joint is modified and consequently the joint kinematics change. This might lead to the development of early patellofemoral osteoarthritis. It is unknown how pain develops in the long-term after a trochleoplasty and if the pain is related to radiological outcomes. Radiological follow-up using MRI and clinical evaluation will provide data to evaluate the effects of this procedure on patellofemoral OA and pain ten years postoperatively.

Study objective

To evaluate the radiological and clinical outcomes 10 years after a trochleoplasty. We are especially interested in the cartilage status and patellofemoral pain of the patients.

Study design

Cohort study, describing the ten year follow-up of a consecutive case series of patients who underwent a trochleoplasty.

Study burden and risks

The patients are invited to visit the Sint Maartschliniek once. The additional time the patient invests in the research is approximately 2 hours. Prior to the examination, the patient is asked to fill out the questionnaires. During the visit, X-rays and an MRI are made. In addition, a physical examination will be conducted. The questionnaires and physical examination will not be additional to the patient. The total amount of radiation of the X-rays is 0.01 mSv and falls within the limit of the International Commission of Radiological Protection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients must have been treated by a sulcus deepening trochleoplasty for recurrent patellar instability with underlying trochlear dysplasia in the

period between April 2004 and October 2014
- Sign informed consent for the proposed study

Exclusion criteria

Patients are excluded if they have a contra-indication for MRI.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-09-2018
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	05-10-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	18-01-2021
Application type:	Amendment
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	ID
CCMO	NL62309.091.17