Difference in patient reported outcomes and patellar tracking before and after isolated MPFL reconstruction.

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Evaluate pre- and postoperative reported outcomes in patients receiving a primary isolated soft-tissue loop MPFL reconstruction for the treatment of patellar instability. Additionally, it is aimed to investigate the difference in patella tracking...

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

Summary

ID

NL-OMON53708

Source
ToetsingOnline

Brief title
4DCT-PROMs-MPFLr

Condition

- Bone and joint therapeutic procedures

Synonym
patellofemoral instability/ patella luxations

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 4DCT, MPFLr, PROMs

Outcome measures

Primary outcome

The main study parameter is the pre- and postoperative difference in patient reported outcome measures (PROMs).

PROMs: KOOS-PS, Kujala kniescore, EQ5D-5L and BPII

Secondary outcome

Difference between pre-operative and one post-operative in patellar tracking, measured with 4DCT. This will be measured before and 12 months after the operation.

Study description

Background summary

A patellar dislocation is one of the most common acute knee disorders in children and adolescents, causing pain and functional decline. In order to restore healthy kinematics and relieve pain, patients can receive a MPFL reconstruction. Still, there is no consensus on the ideal MPFL reconstruction method and many different variations exist. For a reliable comparison, each MPFL reconstruction method should be evaluated clinically. Within the Radboudumc, a dynamic soft-tissue loop method is used for MPFL reconstruction. The method has not yet been evaluated clinically, and the difference in patella tracking is largely unknown.

For a comprehensive description of the background, see section 1 of the research protocol.

Study objective

Evaluate pre- and postoperative reported outcomes in patients receiving a primary isolated soft-tissue loop MPFL reconstruction for the treatment of

patellar instability. Additionally, it is aimed to investigate the difference in patella tracking before and 12 months after surgery measured with 4D CT imaging.

Study design

Prospective single centre observational study

Intervention

n.v.t.

Study burden and risks

CT scans exposes patients to radiation. For this study the level of radiation is estimated as an negligible risk. No additional risks are associated with this study. Potential burdens for patients are predominantly time and additional radiation exposure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

• Age of 16 years and older.
• Recurrent patellofemoral instability, for which:
1) the patient will receive a primary isolated MPFL reconstruction, or
2) the patient has received a primary isolated MPFL reconstruction <12 months ago, on the condition that the patient has completed his/her questionnaires and received a usable preoperative 4D CT scan .
• Informed consent of the patient.

Exclusion criteria

• Patients below an age of 16 years.
• Patients that are pregnant.
• BMI > 35
• Patients that are unable to actively flex and extend their knee.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-02-2023
Enrollment:	15

Type:	Actual

Ethics review

Approved WMO Date:	08-11-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-02-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-12-2023
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
ClinicalTrials.gov	NCT05547269
CCMO	NL82266.091.22