Synovial Involvement in Development of Posttraumatic Osteoarthritis in Patients with Recurring Patellar Dislocations

Published: 12-10-2023
Last updated: 02-12-2024

In this study we try to elucidate the possible contribution of inflammation of the joint mucosa to the development of knee osteoarthritis. If we understand more about the inflammatory processes in the synovium that are important in further...

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

Summary

ID

NL-OMON56210

Source
ToetsingOnline

Brief title
SIDESTEPPED

Condition

- Joint disorders

Synonym
arthrosis, osteoarthritis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Inflammation, Patellar dislocation, Posttraumatic osteoarthritis, Synovium

Outcome measures

Primary outcome

Marker expressions in the blood and mucosal tissue of patients with recurrent

patellar (sub)luxation, indicating the inflammatory status of the patient.

This will be linked to clinical data on pain and function at baseline.

Secondary outcome

Correlation between RNA sequencing data on processes in the synovium and

progression data on pain and function.

Study description

Background summary

People who suffer from a kneecap that repeatedly (sub)luxates undergo surgical treatment for this. It is often seen that the mucous membrane tissue in the joint shows inflammation during the operation. Some of the patients also develop osteoarthritis in the knee. The contribution of the inflammation of the joint mucosa to this is still unknown.

Study objective

In this study we try to elucidate the possible contribution of inflammation of the joint mucosa to the development of knee osteoarthritis. If we understand more about the inflammatory processes in the synovium that are important in further development of osteoarthritis, it will eventually be possible to design a therapeutic approach in order to prevent the development of further damage. One of the options, for example, is the use of stem cells that may be able to influence processes in the mucous membrane.

Study design

Explorative biological analyses in a cross-sectional patient cohort.

Study burden and risks

A study visit with physical examination and blood sampling, and synovial fluid sampling and joint biopsies during surgery. Risk score classification: low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

16 years or older
Patients with a history of recurrent patellar dislocations of the index knee.

Exclusion criteria

Patients with an active inflammatory or infectious co-morbid disease (including rheumatic diseases).
Patients who had previous surgery on the index knee

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-05-2024
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	12-10-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-05-2024
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	NL83924.091.23