Synovial activation In Post-traumatic arthritis Study

Published: 19-12-2019
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Objective: to investigate calcium containing crystal release in synovial fluid after exercise as drivers of synovitis in post-traumatic versus non-post traumatic osteoarthritis.

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

Summary

ID

NL-OMON48619

Source
ToetsingOnline

Brief title
SYNAPS

Condition

- Joint disorders

Synonym
arthrosis, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: reumatologie
Source(s) of monetary or material Support: Ministerie van OC&W,Reumanederland

Intervention

Keyword: mesenchymal stem cell therapy, post-traumatic osteoarthritis, Synovial activation

Outcome measures

Primary outcome

Baseline concentrations and change in crystal concentration before and after exercise in post-traumatic arthritis, post-traumatic OA versus non post-traumatic OA

Secondary outcome

Correlation between crystals in blood and synovial fluid with inflammatory mediators and leucocyte activation

Study description

Background summary

Calcium containing crystal release in synovial fluid after exercise may drive of synovitis in post-traumatic versus non-post traumatic osteoarthritis. They may also cause arthritis soon after initial joint trauma.

Study objective

Objective: to investigate calcium containing crystal release in synovial fluid after exercise as drivers of synovitis in post-traumatic versus non-post traumatic osteoarthritis.

Study design

Study design: Exploratory biologic analyses in a transversal patient cohort.

Study burden and risks

Intervention: blood sampling, synovial fluid sampling before and after physical exercise.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
A study visit involving clinical examination, blood and synovial fluid withdrawal. Risk score classification: low.

Contacts

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Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. 20 patients with a recent anterior cruciate ligament injury
2. 20 patients with a recent meniscal injury
3. 20 patients with post-traumatic osteoartrhritis.

Group 1
18 years or older
Recently (<2 months) suffered a cruciate ligament injury of the index knee.
a swollen joint

Group 2
18 years or older
Recently (<2 months) suffered a meniscal injury of the index knee.

a swollen joint

Group 3
18 years or older
Knee OA according to the clinical ACR criteria for knee OA
Suffered a knee injury (e.g. ligament rupture with subsequent reconstruction) before development of OA in the index knee
a swollen joint

Exclusion criteria

Patients with an active inflammatory or infectious co-morbid disease
Knee prosthesis

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-10-2021
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	19-12-2019

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-06-2021
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	NL66356.091.18