Visualizing Cartilage and Joint Homeostasis Changes after Knee Joint Distraction using the META-Scanner and Synovial Fluid Aspirations*

Published: 24-07-2019
Last updated: 10-04-2024

To gain insight in cartilage and joint biology immediately and up to one year after knee joint distraction using advanced imaging and synovial fluid aspiration, and to additionally measure the change in sodium concentration in cartilage after knee...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON48274

Source
ToetsingOnline

Brief title
META-scanner and SF-markers in KJD

Condition

- Joint disorders

Synonym
cartilage degeneration, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: ReumaNederland

Intervention

Keyword: knee joint distraction, META-scanner, osteoarthritis, synovial fluid

Outcome measures

Primary outcome

The changes in GAG content of the cartilage;

the changes in joint homeostasis that facilitates cartilage repair after knee

joint distraction, with a focus on growth factors, proteases, pro-inflammatory

cytokines, and mesenchymal stem cells;

the changes in sodium concentration of the cartilage.

Secondary outcome

* Relation between imaging parameters and synovial fluid changes

Study description

Background summary

Knee joint distraction (KJD) is a surgical treatment of severe knee OA meant to postpone a total knee arthroplasty (TKA) and has shown significant benefit as well as cartilage regeneration for treated patients in multiple studies.
Multiple studies have been performed to understand the underlying mechanisms, including quantitative MRI imaging (dGEMRIC and T2-mapping) and synovial fluid (SF) aspirations. However, the relatively new 7T META-scanner has the ability to perform gagCEST and sodium imaging, which are techniques that do not require contrast and are related to the GAG content in cartilage. This allows us to gain additional insight in the structure and characteristics of the cartilage that is regenerated after KJD. Furthermore, imaging has so far only been performed before and at least one year after treatment, giving no information on the short to medium-term changes, while SF aspirations have not been done in the months after treatment, likewise giving no information on medium to long-term changes. In this study we want to fill this information gap by including more time points and by performing qualitative MRI scans and SF aspirations at the same time points, in order to relate joint homeostasis

results from SF with changes seen in cartilage on the MRI scans.

Study objective

To gain insight in cartilage and joint biology immediately and up to one year after knee joint distraction using advanced imaging and synovial fluid aspiration, and to additionally measure the change in sodium concentration in cartilage after knee joint distraction.

Study design

Prospective explorative study, with joint fluid sampling and MRI scans

Study burden and risks

Patients will be treated in regular practice by knee joint distraction and have no direct benefit of participating in this study. Results will help to elucidate the underlying mechanisms by which cartilage tissue repair is initiated (as observed during joint distraction) and may provide tools for improvement of (novel) cartilage repair strategies. The MRI scans do not expose the patients to additional risks, while the SF aspirations have a potential (although considered small) chance on diminished clinical effect and an intra-articular infection, although both have not occurred in the previous SF study in KJD patients (NL51539.041.15).

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 with knee joint degeneration (osteoarthritis) eligible in regular clinical practice for knee joint distraction.
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Good knowledge of the Dutch language
- Signed informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Not eligible for MRI, in response to the MRI safety checklist
- Metal present in the treated knee
- Knee width > 14 cm

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO Date:	24-07-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL69657.041.19