# Diagnostic imaging of synovitis in knee osteoarthritis (DISKO)

Published: 30-06-2016
Last updated: 16-04-2024

Our objectives are to assess correlations and relationships between synovitis visualized on non-contrast DESS MRI and: 1) synovitis imaged on CE-MRI; 2) different inflammatory subtypes in OA; 3) other MRI features of OA; 4) knee OA symptoms and 5)...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Synovial and bursal disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON46234

**Source**
ToetsingOnline

**Brief title**
Diagnostic imaging of synovitis in knee osteoarthritis (DISKO)

### Condition

- Synovial and bursal disorders

**Synonym**
Synovitis; mucosal inflammation

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Ministerie van OC&W,Reumafonds

## Intervention

**Keyword:** Knee, MRI, osteoarthritis, synovitis

## Outcome measures

### Primary outcome

Correlations between synovitis visualized on non-contrast DESS and: 1) CE-MRI;

2) Tissue markers of synovial inflammation and specific inflammatory subtypes;

3) Other OA features on MRI; 4) knee OA symptoms and 5) (CE)US findings

related to synovitis.

### Secondary outcome

1. Synovial Ttissue and synovial fluid markers of synovial inflammation and

specific inflammatory subtypes;

2. Other OA features on MRI, particularly compositional and morphological

change in cartilage and meniscus, altered blood perfusion in synovium and

subchondral bone, and osteophyte formation;

3. Knee OA symptoms, especially those related to synovitis (i.e. joint

stiffness, self-reported feeling of swelling, pain patterns (constant versus

intermittent pain)), recorded with validated standardized questionnaires (like

ICOAP, KOOS, VAS and WOMAC).

4. US findings related to synovitis

# Study description

### Background summary

As the prominent role of synovitis in osteoarthritis (OA) and importance of identifying patients with synovitis for targeted treatment are increasingly

recognized, there is growing interest in imaging of synovitis in OA. Contrast-enhanced magnetic resonance imaging (CE-MRI) is the reference standard for visualizing synovitis, but incurs high costs, long scan time and potential health issues in high-risk patients, associated with the contrast agent. A promising recent innovation in MRI of synovitis is rapid diffusion weighted imaging with dual echo steady state (DESS) without the need for a contrast agent. We hypothesize that synovitis imaged with non-contrast DESS MRI shows high correlation with 1) synovitis imaged on CE-MRI; 2) different inflammatory subtypes in OA; 3) other MRI features of OA, 4) knee OA symptoms and 5) synovitis imaged with contrast enhanced ultrasound (CEUS), which is another option to visualize synovitis.

**Study objective**

Our objectives are to assess correlations and relationships between synovitis visualized on non-contrast DESS MRI and: 1) synovitis imaged on CE-MRI; 2) different inflammatory subtypes in OA; 3) other MRI features of OA; 4) knee OA symptoms and 5) synovitis imaged with (CE)US.

**Study design**

Cross-sectional prospective observational study.

**Study burden and risks**

Two MRI sessions, each maximal 45 minutes, and exposure to acoustic noise. No additional risk. No benefit for the patient. There is a very small risk for an allergic reaction when MRI contrast agent is administered. In patients with chronic severe kidney insufficiency (glomerular filtration rate (GFR) < 60 mL/min/1.73m2) the use of this contrast is contraindicated. In order to diminish this risk, patients will be screened before inclusion. Thereby, medication to counteract the reaction is present. The burden for the subject will be minimal. Except drainig a vile of blood, administration of contrast fluid, the burden will mainly exist of time for filling out a questionnaire, undergoing a physical examination, cycling for 10 minutes on a home trainer and MRI acquisition. There will be no direct benefits for the participants in this study. All patients will receive the usual treatment form their treating physician. The patient will also be subjected to an ultrasound examination of the knee for a maximum of 15 minutes. During this session a microbubble contrast, will be administered. For this session the burden for the subject will be minimal. For the patients who will undergo knee surgery, synovial tissue and synovial liquid will be collected during surgery. This is an additional procedure during surgery, but with a relatively low burden. During the MRI examination contrast fluid will be administered intravenously. Therefore an intravenous catheter is placed before the MRI scanBy this intravenous catheter a blood sample is taken for further tests. One vial will

be sufficient. The blood will be tested for example on biomarkers of inflammation.

# 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

- Age * 18 years;
- Clinical signs of knee OA: knee pain (numeric rating scale > 3);
- Radiographic signs of knee osteoarthritis (radiographic Kellgren and Lawrence grade *1 );
- Signs of synovitis (i.e. joint effusion) on physical examination of the knee;

### Exclusion criteria

- Subjects with a typical (e.g. metallic foreign bodies, etc.) contra-indication for an MRI exam;
- Renal insufficiency, checked with blood sample test (GFR < 60 ml/min/1,73 $m^2$);
- Known allergy to contrast agents;
- Known pulmonary hypertension
- Woman who are pregnant or lactating

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 18-05-2017 |
| Enrollment: | 60 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 30-06-2016 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 27-06-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

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| Approved WMO Date: | 04-09-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 12-10-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL57741.078.16 |