# 3D joint space evaluation in knee osteoarthritis: The importance of weightbearing and flexion

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To evaluate how the 3D knee joint space distribution in knee OA patients changes under the influence of weight-bearing (upright) and flexion MRI scanning.

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

# **Summary**

### ID

NL-OMON54070

**Source** ToetsingOnline

Brief title Weight-bearing and flexed MRI in knee OA

# Condition

• Joint disorders

**Synonym** osteoarthritis

**Research involving** Human

### **Sponsors and support**

Primary sponsor: Universitair Medisch Centrum Utrecht Source(s) of monetary or material Support: Vrienden van het UMC Utrecht

### Intervention

Keyword: joint space width, knee, osteoarthritis, weight-bearing

#### **Outcome measures**

#### **Primary outcome**

The primary study parameter is the change in median medial joint space width

between the different positions (weight-bearing/non-weight-bearing and

flexion/extension).

#### Secondary outcome

Secondary study parameters are:

- 1. Median lateral joint space width
- 2. Joint space shift size and direction
- 3. Change in distance distribution

# **Study description**

#### **Background summary**

Osteoarthritis (OA) is mainly characterized by cartilage degeneration. In knee OA, measuring the distance between the tibia and femur, known as the joint space width (JSW), is an often-used method to quantify the progression of the disease or the effectiveness of treatments, because it is an indirect measure of cartilage degeneration. However, JSW is often measured while the patient is standing (weight-bearing) with slightly flexed knees, with a flexion angle of around 7-10 degrees, while direct cartilage thickness measurements are usually performed while the patient is lying down (non-weight-bearing) with an extended leg. Because of this difference in positioning, it is difficult to compare different JSW and cartilage thickness measures, as it is not clear what happens with the JSW distribution in the joint when a patient changes position between weight-bearing/non-weight-bearing and flexion/extension. In this study, we aim to identify the changes that occur in the knee of OA patients under the influence of weight-bearing and/or flexion, to enable comparing joint space measures from different positions. In this research we want to use MRI as a

three-dimensional imaging technique because there is no radiation involved.

#### **Study objective**

To evaluate how the 3D knee joint space distribution in knee OA patients changes under the influence of weight-bearing (upright) and flexion MRI scanning.

#### Study design

Explorative cross-sectional study.

#### Study burden and risks

Patients need to visit the University of Twente once. The total duration of the visit is 1 hour. To perform the upright scan, the participant needs to stand still for at most 15 minutes. During this position, some people may experience dizziness. If this is noticed, the scan will be aborted immediately and the participant is turned back to the horizontal position. The risks associated with this MRI examination are negligible.

# Contacts

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years)

### **Inclusion criteria**

- Patients with symptomatic knee osteoarthritis in at least one knee
- > 18 years old
- Kellgren-Lawrence grade (severity) 2 or 3
- Good knowledge of the Dutch language
- Signed informed consent

### **Exclusion criteria**

- Previous surgery in (both) symptomatic knee(s)
- Inability to stand for 15 minutes, without assistance
- Unable to fit knee in the MRI coil (knee width >  $\sim$ 15 cm)
- Not eligible for MRI, in response to the MRI safety checklist

# Study design

# Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	22-11-2023
Enrollment:	21
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	28-04-2023
Application type:	First submission
Review commission:	METC NedMec

# **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** CCMO

ID NL73375.041.20