

# Qualitative imaging of cartilage and bone in end stage knee osteoarthritis treated with knee joint distraction or high tibial osteotomy.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON39812

### Source

ToetsingOnline

### Brief title

Qualitative imaging of OA upon KJD or HTO

### Condition

- Joint disorders

### Synonym

joint degeneration, osteoarthritis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W,ZonMW

## Intervention

**Keyword:** cartilage changes, CT, MRI, osteoarthritis

## Outcome measures

### Primary outcome

The following parameters will be compared between pre-, 1 year, and 2 years post treatment for KJD and pre- and 2 years post treatment for HTO:

1. the change in cartilage \*proteoglycan content\*
2. the change in \*collagen content/distribution\*
3. the change in \*bone marrow lesions\*
4. the change in \*3D bone density\*

And secondary:

1. is there a mutual relation between quantitative cartilage and bone changes
2. is there a relation between qualitative cartilage and bone changes with those of quantitative changes in the cartilage as measured in the original RCTs.
3. is there a relation of (combinations of) changes in qualitative and quantitative parameters of bone and cartilage to clinical benefit of KJD and HTO

### Secondary outcome

n.a.

## Study description

## Background summary

Cartilage and bone changes induced by knee joint distraction, and more recently suggested to occur by osteotomy as well, is difficult to evaluate objectively. There are only surrogate markers like sophisticated MRI and CT analyses for evaluating cartilage and bone quality. Recently two prospective trials randomising a total knee prosthesis (TKP), with knee joint distraction (KJD), and randomising high tibial osteotomy (HTO) with KJD were started, evaluating clinical benefit and quantitative cartilage changes.

## Study objective

In the present study we evaluate the change in quality of cartilage and bone as a result of KJD and of HTO. Based on the results of this pilot study, we will design a clinical study, with sufficient power, using the most promising sequences to evaluate cartilage and bone changes accurately after treatment.

## Study design

This is a 2 year follow-up observational pilot study.

## Study burden and risks

There is no direct benefit for the patients when participating in this pilot study. By participating in the study, patients contribute to further valuable developments in knowledge on joint tissue repair by use of surrogate imaging markers for cartilage and bone quality characteristics in general and specifically due to KJD and to HTO. All proposed imaging techniques are already used in clinical practice.

The risk for patients is minimal; there is a negligible risk due to x-ray radiation and a minimal risk due to use of intra venous contrast agent.

## Contacts

### Public

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### Scientific

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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 randomized to Knee joint distraction or High tibial osteotomy in either of the two recently started trials.

### Exclusion criteria

Patients with risks due to the magnetic field of the MRI such as those with pacemakers, nerve stimulators, metal implants, stents, clips, etc

Patients with a known anaphylactic reaction to gadolinium or related substances

Patients with (a history of) kidney disease or with a kidney transplantation

Patients with a glomerular filtrationrate of  $<60$  ml/min/1,73m<sup>2</sup>

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2012
Enrollment:	41
Type:	Actual

## Ethics review

Approved WMO	
Date:	07-02-2012
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	11-03-2014
Application type:	Amendment
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	ID
CCMO	NL38442.041.11