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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	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
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508 GA
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100

Utrecht 3508 GA
NL

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/1,73m2

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