Radiological evaluation of CT based vs MRI based Signature* for total knee arthroplasty

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PrimaryTo evaluate the alignment of the Signature* CT-based procedure compared to the Signature* MRI-based instruments.SecondaryTo evaluate the efficacy of the CT-based Signature* procedure in terms of operation time compared to the Signature* MRI-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON40504

Source
ToetsingOnline

Brief title
CT vs MRI based Signature* for TKA

Condition

- Bone and joint therapeutic procedures

Synonym
knee wear, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Orbis Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: alginement, CT, MRI, navigation, total knee arthroplasty

Outcome measures

Primary outcome

Outliers in alignment of the femoral and tibial prosthesis in the frontal

plane, measured on radographs made 6 weeks after operation and compared between

the CT-based Signature* procedure and the standard MRI-based Signature*

Occurrence (and percentage) of outliers in alignment in the frontal, sagittal

and horizontal plane of femoral and tibial components.

Occurrence (and percentage) of outliers in alignment of the mechanical axis of

the leg.

Difference in thickness of the in vivo inserted polyethylene compared to

pre-operatively calculated thickness of this

insert.

Accuracy of the guides

Secondary outcome

Operation time

Fit, form and practical use of the Signature* alignment guides.

Needed change of plans per-operative: change of size of prosthesis, conversion

Signature procedure to conventional

procedure for any reason

Study description

Background summary

Signature* for total knee arthroplasty (TKA) is a patient specific alignment guide based on MRI-images or a CT-scan.
This type of guiding makes conventional guiding unnecessary.
The principle aims of this study are: to investigate whether the CT-based Signature* for TKA, is at least as effective
in radiological outcome as the Signature* based on MRI and to investigate whether Signature* CT-based results in a
larger percentage of prosthesis placed correctly (within guidelines of 3 degrees varus and 3 degrees valgus).
Furthermore, a third aim of

Furthermore, a third aim of the study is to compare the preoperatively planned alignment of the prothesis with the
actual alignment in vivo.

Study objective

Primary
To evaluate the alignment of the Signature* CT-based procedure compared to the Signature* MRI-based instruments.
Secondary
To evaluate the efficacy of the CT-based Signature* procedure in terms of operation time compared to the Signature* MRI-based instruments
To evaluate the safety of the CT-based Signature* procedure in terms of needed change of plans compared to the Signature* MRI-based instruments

Verify the fit, form and practical use of the CT-based Signature* compared to the Signature* MRI-based instruments:
To determine the occurrence (and percentage) of outliers in alignment in the frontal, sagittal and horizontal plane of femoral and tibial components.
Outliers are defined as deviations > 3 degrees from preoperative planning.
To determine the occurrence (and percentage) of outliers in alignment of the mechanical axis of the
leg. Outliers are defined as deviations > 3 degrees from preoperative planning.
Verify to what extend the thickness of the in vivo inserted polyethylene corresponds with the preoperatively
calculated thickness of this insert.

Study design

A Prospective, Randomized study
Patients will be randomized to be operated on with the use of the MRI -based Signature*(control group), or
CT-based Signature* (trial group). Patients have an equal opportunity of being

assigned to the trial group or control group. The
randomization will occur via a random number generator. The surgeon or clinical researcher does not choose the
participants for each group. The patients are informed on the type of prosthesis placement that has been carried
out.

Intervention

NA

Study burden and risks

The CT scan uses radiation. This radiation can be detrimental when administered in high doses. However, it is expected that the radiation dose that will be used, will not have significant negative side effects on the health of the patients.

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 scheduled to undergo primary TKA replacement with any of the following indications
*Painful and disabled knee joint resulting from osteoarthritis.
*High need to obtain pain relief and improve function,
-Body-mass-index (BMI) <35
-Ablility and willingness to follow instructions, including control of weight and activity level, and to return for follow-up evaluations.
-Consent form read, understood and signed by patient.

Exclusion criteria

-Active infection in knee
-General infection
-Distant foci of infections which may spread to the implant site
-Failure of previous knee joint replacement
-Pregnancy
-Previous major knee surgery, except for arthroscopic meniscectomy.
-Metal near knee joint (MRI-scan not possible)
-Not able or willing to undergo MRI-scan or CT-scan
-Reumatoid arthritis
-Non-correctable varus axis

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2014
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	27-02-2014
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL46625.096.13

Study results

Date completed:	31-12-2015

Actual enrolment: 140