Comparison of Signature* Personalized Patient Care versus the intramedullary alignment guides by computer-navigated registration of bone cuts in Total Knee Arthroplasty

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Comparing the Signature* alignment guides with the conventional intramedullary alignment guides by comparing the (proposed) bone cuts of Signature* with the actual bone cuts of the conventional intramedullary alignment guides.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON33295

Source
ToetsingOnline

Brief title
Signature* Personalized Patient Care

Condition

- Bone and joint therapeutic procedures

Synonym
gonarthrosis, knee wear

Research involving
Human

Sponsors and support

Primary sponsor: Orbis Medisch Centrum
Source(s) of monetary or material Support: financiering vanuit maatschap orthopedie

Intervention

Keyword: Patient specific alignment guides, Total Knee Replacement

Outcome measures

Primary outcome

Cutting plane angles

Secondary outcome

resection level

Study description

Background summary

The Biomet Signature* product for Total Knee Arthroplasty provides for patient specific alignment guides based on MRI-images. These guides are applied during the operative procedure and make intramedullar guiding unnecessary. Therefore, the surgical procedure will be less invasive with shorter intervention time with less surgical intruments needed. Also, application will probably result in reduced blood loss and a lower thromboembolic complication rate. With the patient-specific Signature* guides and 3D MRI-images, the surgeon can probably determine preoperatively the ideal size and positioning of the prosthesis and placement will probably be more precise.

Before aligning knee prosthesis according to the Signature guides, a comparison of the allignment with the conventional method is desired.
the hypothesis of the study is that the bone cuts made according tot the signature guides are comparable to those of the conventional intramedullary guides.

Study objective

Comparing the Signature* alignment guides with the conventional intramedullary alignment guides by comparing the (proposed) bone cuts of Signature* with the

actual bone cuts of the conventional intramedullary alignment guides.

Study design

Clinical , non-randomized sudy

Placement of a Biomet Vanguard* knee prosthesis is done according to the conventional standard intramedullary alignment guide. During surgery, Stryker precisioN* Knee Navigation System is applied so cutting plane angles and resection levels for both Signature* guides and conventional intramedullary guides can be registered and compared.

Study burden and risks

All patients have the standard risk for a Vanguard* Complete Knee System. Time of surgical intervention is expected to be ten to thirty minutes longer as a result of applying the navigation system and registering the cutting plane angles. Application of the navigation system requires placement of two additional percutaneous pins in both femur and tibia, which will be removed during the procedure. Preceding surgery, the patient will undergo a MRI-scan of hip, knee and ankle. All patients will obtain the standard rehabilitation protocol.

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

painfull and disabled knee joint resulting from osteoarthritis where one or more compartments are involved
high need to obtain pain relief and improve function
above 18 years old
body mass index (BMI) <30
Able and willing to follow instructions
informed consent

Exclusion criteria

active infection in the knee
general infection
distal foci of infections which may spread to the implant site
faillure of previous joint replacement
pregnancy
previous osteotomy
Prostesis (hip, knee or ankle), intramedullary fixation or any kind of metal in the lower extremities

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-07-2009
Enrollment:	14
Type:	Anticipated

Medical products/devices used

Generic name:	precisioN Knee Navigation System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	14-09-2009
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	NL27772.096.09