Clinical evaluation of Signature Personalized Patient Care Prospective, clinical, multicentre, randomised, double blind study

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Primary objectives* To evaluate the initial and long-term clinical results in terms of function, quality of life and pain/satisfaction of the Signature* procedure compared to the standard operation instruments (Vanguard CR cemented fixation).* To...

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

Summary

ID

NL-OMON35099

Source
ToetsingOnline

Brief title
Clinical evaluation of 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 door normale DBC-systeem

Intervention

Keyword: Clinical outcome, Patient specific alignment guides, Total Knee Replacement

Outcome measures

Primary outcome

Primary endpoints

* American Knee Society Score at 2 year post-operative.

* Radiographic evaluation at 6 weeks post-operative.

Secondary outcome

Secondary endpoints

* KSS, WOMAC, VAS, Oxford Knee * 12, EQ-5D at each post-operative visit.

* Operation time

* Blood loss

* Length of hospital stay

* Complications/adverse events

* Needed change of plans and reasons for changes

* Survivorship at 10 years post-operative

* Wear rate measured by radiographic evaluation at 1 Y, 2 Y, 5 Y and 10 Y

post-operative.

* All material Costs and EQ-5D during inpatient fase of study.

Study description

Background summary

Signature* Personalized Patient Care (Biomet) is a recently introduced product for alignment of the knee during TKA for placement of the Vanguard* Complete Knee System. This new patient-specific guide is an extramedular instrument that makes intramedullar alignment unnecessary. Signature* will be created from a Magnetic Resonance Imaging scan (MRI). Using software (Materialise, Leuven, Belgium), the MRI scan will be segmented and assembled into a 3-Dimensional model. The Signature* alignment guide will be created for both the femur (Figure 1), that allows the surgeon to place pins for the distal cut block and drill holes for the 4-in-1 block, and the tibia (Figure 2) that allows the surgeon to place the pins for the tibial resection block.
With Signature* it is possible to plan the total knee replacement, the position and size of the prosthesis accurately prior to surgery.
Lombardi et all. tried to find out if Signature* was applicable to assist as an alignment guide during TKA. They analysed 52 knees aligned with Signature*. They found that operation time was 10 minutes shorter (77 vs. 87 minutes; P=.03) for the second 26 TKA, compared to the first 26 TKA. perioperative blood loss was low (averaged 52cc with a range of 45-100cc) and there were no complications intraoperatively. Also was found that the Knee Society Score, pre-operative compared with post-operative was improved (KSS-pain: 8 to 38, P<.0001; KSS-function: 58.1 to 64.1, P=NS) 19.
First, Signature* placement is expected to be at least as precise as with conventional intramedullary guiding because computer software is used to determine the correct position of the prosthesis. Therefore, the survival of the prosthesis is expected to be better because of less polyethylene wear in the long term.
Second, the Signature* surgical procedure is expected to result in a slightly reduced blood loss and a lower thromboembolic complication rate, compared to conventional intramedullary guiding because no entrance into the medullary cavity of the bone needs te be made.
Third, this method for alignment of the knee is expected to result in shorter surgical operation time because it is less invasive and less surgical instruments are needed.
However, no additional studies to the study of Lombardi et al. have yet been conducted on the Signature alignment guide sofare. Therefore, the aims of this study are: to prove that the new device, Signature* Personal Patient Care for Total Knee Arthroplasty, is at least as effective in clinical outcome as the widely used current method for total knee arthroplasty, the conventional Vanguard CR cemented fixation, and results in placement that is at least as precise as with the conventional method.

Study objective

Primary objectives
* To evaluate the initial and long-term clinical results in terms of function, quality of life and pain/satisfaction of the Signature* procedure compared to the standard operation instruments (Vanguard CR cemented fixation).
* To evaluate the alignment of the Signature* procedure compared to the

standard operation instruments (Vanguard CR cemented fixation).

Secondary objectives
* To evaluate the efficacy of the Signature* procedure in terms of operation time, bloodloss and length of hospital stay compared to the standard operation instruments (Vanguard CR cemented fixation).
* To evaluate the safety of the Signature* procedure in terms of complications/adverse events and needed change of plans compared to the standard operation instruments compared to the standard operation instruments (Vanguard CR cemented fixation).
* To evaluate the survival and wear rate of the polyethylene insert of the Signature* alignment guide compared to the standard operation instruments (Vanguard CR cemented fixation).
* To evaluate the cost-effectiveness of the Signature* procedure compared to the standard operation instruments (Vanguard CR cemented fixation).

Study design

Prospective, multicenter, randomised, double-blind, controlled trial.
Two Dutch hospitals participating:
* Orbis Medical Park, Sittard, the Netherlands.
* St. Anna Hospital, Geldrop, the Netherlands.

Patients will be randomized to be operated on with the use of the conventional alignment method (control group), or Signature* Personalized Patient Care (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 stratified to hospital, meaning that in each hospital half of the patients will obtain the trial implant.
The patients are not informed on the type of prosthesis that is being placed.
The outcome assessor is blinded to the treatment allocation of the patients.

Intervention

Biomet Signature* Personalized Patient Care
Signature* Personalized Patient Care utilizes patient specific femoral and tibial positioning guides, developed from MRI. The guides are made of polyamide and are disposable.
The Signature* system, which fits the femoral and tibial components independently, is used with the Vanguard* Complete Knee System. This prosthesis is designed for achieving 145 degrees of flexion and has a broad range of available implant sizes.

Study burden and risks

Risks are those associated with placement of the Vanguard* Complete Knee System.
Theoretical disadvantage of the use of the Signature* alignment guide is the possible occurrence of allergic reactions. Preliminary to surgery (6 weeks), the patient will undergo a MRI-scan of hip, knee and ankle.
All patients will obtain the standard rehabilitation protocol. During the standaard outpatient visits (pre-operatively, 6 weeks, 3 months, 1 year, 2 years, 5 years and 10 years) standard questionnaires (applying also to non-study patients) concerning knee function and pain will be taken. Additionally, standing, weight-bearing long-leg X-rays will be made instead of standard X-rays in non-study patients.
The clinical results of the Signature knee are unknown, however, they are expected to be equal to the conventional total knee arthroplasty.
Operation time is expected to be shorter with the use of the Signature* alignment guide but has not yet been proven in clinical trials.
Blood loss is expected to be less with Signature total knee arthroplasty but has not yet been proven in clinical trials.
Signature total knee arthroplasty is expected to give a longer survival, however, this is not clinically confirmed.

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

Painful and disabled knee joint resulting from osteoarthritis
One or more compartments are involved, as assessed by X-ray
High need to obtain pain relief and improve function
Above 18 years old (full skeletal maturity)
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 joint replacement
Pregnancy
Previous major knee surgery, except for arthroscopic meniscectomy
Use of anticoagulants for any reason
Metal near knee joint (MRI-scan not possible)
Not able or willing to undergo MRI-scan

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-09-2010
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	25-05-2010
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	NL31469.096.10