Clinical Evaluation Of Vanguard Deep Dish Rotating Platform Knee Prosthesis

Published: 25-06-2009 Last updated: 06-05-2024

1: Comparing the initial and long term clinical results and survival of the Vanguard Deep Dish prosthesis with the traditional Vanguard Fixed bearing prosthesis.2: Does Joint Care improves the recovery process?

Ethical review Approved WMO **Status** Recruitment stopped

Health condition type Bone and joint therapeutic procedures

Study type Interventional

Summary

ID

NL-OMON33907

Source

ToetsingOnline

Brief title

Vanguard Deep Dish

Condition

Bone and joint therapeutic procedures

Synonym

arthritis of the knee, gonartrosis

Research involving

Human

Sponsors and support

Primary sponsor: Biomet Nederland BV

Source(s) of monetary or material Support: Biomet

Intervention

Keyword: gonarhtrosis, knee prosthesis, rotating platform, survival

Outcome measures

Primary outcome

American Knee Society Score at 2 year postoperative

Secondary outcome

Patient success at 2 year postoperative (see the definition in *Study

Definition* section).

American Knee Society Score at each postoperative visit.

Radiographic evaluation at each postoperative visit.

Adverse events.

Survivorship at 10 year postoperative.

Patient satisfaction as determined by answers to patient outcomes questionnaires

Wear using rsa

Study description

Background summary

The mobile bearing knees have the theoretical advantages of potentially minimizing the polyethylene wear and reducing the incidence of implant loosening, which were recognized as the major causes of failure of total knee replacements. The aims of this study are to prove that the new device, the Vanguard Deep Dish Rotating Platform (DD RP), is at least as effective in clinical outcome as a widely used current design of knee replacement, the Vanguard fixed bearing, and better in long term survivorship.

Study objective

1: Comparing the initial and long term clinical results and survival of the Vanguard Deep Dish prosthesis with the traditional Vanguard Fixed bearing

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prosthesis.

2: Does Joint Care improves the recovery process?

Study design

International, multicenter, randomised, controlled trial

Intervention

total knee replacements with either Vanguard Deep Dish rotating platform or Vanguard fixed bearing

Study burden and risks

All patients have the standard risk for a total knee prosthesis. The clinical results of the Vanguard Deep Dish knee are unknown, however they are expected to be equal to the Fixed Bearing knee. The Vanguard Deep Dish is expected to give a longer survival, however this is not clinical confirmed. The patient will obtain the standard rehabilitation protocol. During the standard outpatient visits (preoperatively, 6 weeks, 6 month 2,3,5,7, and 10 years postoperatively) additional questionnaires concerning knee function and pain will be taken.

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 with a pre-operative knee score of < 70.

Patients scheduled to undergo primary total knee replacement because of a painful and disabled knee joint resulting from osteoarthritis.

Ability and willingness to follow instructions and to return for follow-up evaluations.

Patients who are at least 18 years of age.

Consent form read, understood, and signed by patient.

Exclusion criteria

Infection.

Osteomyelitis.

Previous partial or total prosthetic knee replacement on the operative side.

Sepsis.

Patients who had body mass index >40

Study design

Design

Study phase: 4

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Control: Active

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-06-2010

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date: 25-06-2009

Application type: First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 14-11-2017

Application type: Amendment

Review commission: METC Atrium-Orbis-Zuyd

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

ClinicalTrials.gov NCT00753090 CCMO NL24052.096.08