# Clinical Evaluation Of Vanguard Deep Dish Rotating Platform Knee Prosthesis

Published: 25-06-2009
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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?

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| **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

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

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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

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| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |

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|---|---|
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 04-06-2010 |
| Enrollment: | 100 |
| Type: | Actual |

## Ethics review

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| 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 |