Post-market Clinical Follow-up Study to Provide Safety, Performance and Clinical Benefits Data of the Vanguard PS Open Box Porous Femoral (Implants and Instrumentation) - A Consecutive Series Study

Published: 22-04-2024
Last updated: 07-03-2025

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56781

Source
ToetsingOnline

Brief title
PILLAR

Condition

- Other condition

Synonym
arthroplasty, osteoarthritis, prostheses

Health condition

bewegingsapparaat

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Zimmer Biomet,ZimmerBiomet

Intervention

Keyword: benefits, clinical, data, follow-up, implants, instrumentation, performance, post-market, safety

Outcome measures

Primary outcome

Assessment of safety by recording and analyzing the incidence and frequency of

revisions, complications and adverse events. Relation of the events to implant,

instrumentation and/or procedure should be specified.

Secondary outcome

Performance and clinical benefits demonstrated by PROMs (patient-reported

out-come measures).

Radiographic Outcomes from conventional X-rays and evaluation of induced micro

motion using CT-scans and valgus-varus loading of the knee joint.

Study description

Background summary

Post-market Clinical Follow-up Study to Provide Safety, Performance and
Clinical Benefits Data of the Vanguard PS Open Box Porous Femoral (Implants and

Instrumentation)

Study objective

The objective of this retrospective consecutive series PMCF study is to collect long-term data confirming safety, performance and clinical benefits of the Vanguard PS Open Box Porous Femoral (implants and instrumentation) when used for total knee arthroplasty.

The primary objective is the assessment of safety by analyzing implant survivorship. This will be established by recording the incidence and frequency of revisions, complications and adverse events. Relation of the events to implant, instrumentation and/or procedure should be specified.

The secondary objective is the assessment of performance and clinical benefits by recording patient-reported clinical outcome measures (PROMs) as well as radiographic outcomes (conventional bi planar x-rays and CT-scan).

Study design

Monocentric, Consecutive series

Study burden and risks

Subjects who meet the indications and none of the contraindications will be contacted by the investigator and offered participation in the study. The investigator should introduce the clinical study to the subject by explaining the clinical study plan, procedures and objectives. A Patient Information and Consent Form as well as a General Data Protection Regulation notice (GDPR notice) and the questionnaires will be provided to all patients when coming back for the follow-up visit. During this visit the patients will be able to ask any questions regarding the study participation. Once all questions could be answered, the patient will decide on their study participation.

When the subject has decided to participate a visit will be scheduled in which the following data will be collected: Pain and functional performance as reported by PROMs (OKS, KOOS), Clinical examination: pain scores, range of motion, walking distance), Radiographic outcome: evaluation of conventional x-rays and evaluation of induced micro motion using CT-scans under valgus-varus load, Complications/Adverse Event and date of its occurrence (relation to implant, instrumentation and/or procedure should be specified), Implant removal/revision, date of revision and reason (relation to implant, in-strumentation and/or procedure should be specified)

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

This study is focused on patients treated with the Vanguard PS Open Box Porous Femoral between 2009 and 2013 within the Amsterdam UMC, location AMC.
The Vanguard PS Open Box Porous Femoral prosthesis is indicated for patients treated for:
• Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
• Correction of varus, valgus, or posttraumatic deformity.
• Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

Additionally, in order to be eligible to participate in this study, a subject

must meet the following criteria:
• The participant must be able to understand the Dutch language in order to complete the questionnaires.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Off label use.

Absolute contraindications include:
• Infection.
• Sepsis.
• Osteomyelitis.

Relative contraindications include:
• An uncooperative patient or a patient with neurologic disorders who is incapable of following directions.
• Osteoporosis.
• Metabolic disorders which may impair bone formation.
• Osteomalacia.
• Distant foci of infections which may spread to the implant site.
• Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram.
• Vascular insufficiency, muscular atrophy, neuromuscular disease, and/or incomplete or deficient soft tissue surrounding the knee.

Subgroup exclusion criteria:
• For the subgroup analysis to determine variability in methodological error, bilateral patients are excluded from the subgroup since they will already be exposed to an additional scan.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-05-2024
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	The Vanguard Knee System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-04-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL85030.018.23