Post Market Clinical Follow-up Study on the Refobacin Revision-3 Bone Cement and its instrumentation

Published: 26-03-2025
Last updated: 19-04-2025

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Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON57380

Source
ToetsingOnline

Brief title
Refobacin Revision PMCF

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
explantation, revision

Research involving
Human

Sponsors and support

Primary sponsor: Zimmer Biomet
Source(s) of monetary or material Support: Zimmer Biomet

Intervention

Keyword: Bone cement, Knee arthroplasty, Knee revision

Outcome measures

Primary outcome

The primary endpoint is defined by the survival of the implant system at 3, 5, and 10 years which is based on removal of any metal components of the hip or knee implants used in combination with the Refobacin Revision-3 Bone Cement and will be determined using Kaplan Meier method.

The safety of the system will be assessed by monitoring the frequency and incidence of adverse events. Relation of the events to bone cement, implant, instrumentation and/or procedure should be specified.

Secondary outcome

The secondary endpoints of this study are defined by the performance and clinical benefits of Refobacin Revision-3 Bone cement which will be assessed by the standard scoring system (PROMs) at each follow up time-point.

Study description

Background summary

To prevent the development of a periprosthetic joint infection, Zimmer Biomet has developed a bone cement called Refobacin Revision, which contains the antibiotics clindamycin and gentamicin; the combination of the two antibiotics, which target different kinds of bacteria, is known to have an antibacterial effect on more than 90% of the bacteria common to infected cases.
This is a Post-Market Clinical Follow-up (PMCF) study to fulfil the post-market surveillance obligations according to Medical Device Directive, MEDDEV 2.12-2 and the Medical Devices Regulation (MDR 2017/745). The data collected from this study will serve the purpose of confirming safety, performance and clinical benefits of the Refobacin Revision-3 and its instrumentations when used in hip

and knee revision surgeries.

Study objective

The objectives of this study are to confirm safety, performance and clinical benefits of the Refobacin Revision-3 Bone Cement and its instrumentation, when used in hip or knee revision surgeries, by analysis of standard scoring systems, radiographs and adverse event records.
The safety of the system will be assessed by monitoring the frequency and incidence of adverse events as well as any revision of cemented metal components to the joint. Relation of the events to cement, implant, instrumentation and/or procedure should be specified.
The performance and clinical benefits will be evaluated by assessment of the overall pain and functional performance, subject quality of life, and radiographic parameters of all enrolled study subjects.

Study design

Retrospective and prospective, consecutive, multicenter, non-controlled study.
Sub group: StageOne spacer cohort.

Study burden and risks

The foreseeable risks and possible side effects associated with surgery were explained to you in details by your surgeon before the operation.
There are no additional risks related to your participation in the study.
The patients will have no direct benefit from taking part in this study.
However, the information we get from documenting the outcome of your surgery will help us measure the safety and performance of this procedure and assess whether it can provide long-term benefits to many other patients.
Participating in the study may have the following disadvantages:
- Participation in the study costs the patient extra time, because 2 additional postoperative follow-up visits in the hospital are planned.
- These visits include taking an x-ray of the operated joint.

Contacts

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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

• Patient is 18 years or older and skeletally mature.
• Patient is capable of understanding the surgeon*s explanations and following his instructions, able and willing to participate in the follow-up program.
• Patient gave consent to take part in the study by signing the EC approved Informed Consent Form (ICF).
• Patient who underwent or will undergo a hip or knee revision surgery with a Zimmer Biomet implant and the Refobacin® Revision-3 Bone Cement.
• Patient meets at least one of the following indications, as stated in the IFU:
- Patients requires a revision operation resulting from aseptic loosening of the prosthesis and/or infection of the prosthesis by gentamicin and/or clindamycin sensitive strains.
- Patients undergoing a two-stage revision that requires the fabrication and fixation of short-term total or hemi joint StageOne* spacers. The device is intended for use in conjunction with systemic antimicrobial therapy (standard approach to an infection).

Additional inclusion criteria for patients receiving a StageOne* spacer, as stated in the IFU:
o Implantation period of a maximum of 180 days.
o The molded temporary prosthesis is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers)

throughout the implant period.

Exclusion criteria

• Patient is unwilling or unable to give consent or to comply with the follow-up program.
• Patient is known to be pregnant or breastfeeding.
• Patient has any condition that would, in the judgment of the Investigator, place the patient at undue risk or interfere with the study.
• Patient is a vulnerable subject (prisoner, mentally incompetent or unable to understand what participation to the study entails, a known alcohol or drug abuser, anticipated to be non-compliant).
• Patient has plans to relocate during the study follow-up period.
• As stated in the IFU, patient with known hypersensitivity to gentamicin and/or clindamycin and/or to other constituents of the bone cement.
• Additional exclusion criteria for patients receiving a StageOne* spacer, as stated in the IFU:
- The infected Total Hip/Knee Replacement (THR/TKR) devices cannot be removed.
- A systemic or secondary remote infection is expected or confirmed.
- Lack of adequate bone structure precludes adequate support of the prosthesis in the proximal femur or acetabular region, or
- Lack of adequate competence (anatomical and functional) of peripheral ligamentous apparatus and extensor mechanism.
- The patient is sensitive (allergic) to aminoglycosides

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	108

Type:	Anticipated

Medical products/devices used

Generic name:	Refobacin Revision bone cement
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-03-2025
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NCT06699160
CCMO	NL87879.100.24