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Post-market clinical follow-up study for Zimmer femoral nails

Submission date
20/11/2025

Recruitment status
No longer recruiting

Registration date
18/12/2025

Overall study status
Ongoing

Last Edited
26/11/2025

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looks at the safety and performance of two types of Zimmer Natural Nails used to treat broken thigh bones (femur) or planned bone cuts (osteotomies). These nails are metal rods placed inside the bone to help keep it stable while it heals. The study will review past patient records and ask patients about their recovery to confirm how well these devices work.

Who can participate?
People who have already had surgery using either the Antegrade Femoral Nail or the Retrograde Femoral Nail can take part. Patients who had the nails used for reasons other than treating a femur fracture, have certain medical conditions, poor bone quality, or are under 18 years cannot take part. Patients who have opted out of sharing their health data nationally will also be excluded.

What does the study involve?
If you are eligible, you will receive a letter and information about the study. About 3–4 weeks later, the study team will call you to answer any questions. If you agree to take part, you will give verbal consent over the phone. The team will then ask you a few questions about pain and how well your hip or knee works. They will also review your medical records, including details of your surgery, X-rays, and any complications. All information will be stored securely and only the study team will have access.

What are the possible benefits and risks of participating?
There are no risks or extra procedures involved. The study will not change your treatment or provide any direct health benefits. It simply collects information to help improve care in the future.

Where is the study run from?
The study is being carried out at William Harvey Hospital in Ashford and Queen Elizabeth the Queen Mother Hospital in Margate, both part of East Kent Hospitals NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
The study starts on 10 March 2025 and will finish on 31 January 2026

Who is funding the study?
Zimmer Biomet (USA)

Who is the main contact?
Mr Raman Raj Thakur, raman.thakur@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
339982

Protocol serial number
MDRG2017-89MS-182T

Study information

Scientific Title
Post-market clinical follow-up study to provide safety, performance and clinical benefits data of the Zimmer® Natural Nail® antegrade and retrograde femoral nail (implants and instrumentation) – a retrospective consecutive series study

Study objectives
The objective of this retrospective post-market clinical follow-up (PMCF) study is to collect data confirming safety, performance and clinical benefits of the Zimmer Natural Nail Antegrade and Retrograde Femoral Nail (implants and instrumentation) when used for temporary stabilization and fixation of femoral fractures and/or osteotomies.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 04/02/2025, South Central - Berkshire B Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8029; berkshireb.rec@hra.nhs.uk), ref: 24/SC/0317

Study design
Single-center, retrospective, consecutive series of patients

Primary study design
Observational

Study type(s)
Efficacy, Safety, Treatment

Health condition(s) or problem(s) studied
Femoral shaft fractures

Interventions
The study only be will cover two designated hospitals in England. We will identify a list of patients who underwent treatment of femur fractures with antegrade nail (nail introduced from the hip) and retrograde nail (nail introduced from the knee) from the hospital trauma database which is a database for all patients seen in the hospital with fractures. We will aim to collect a total of 94 consecutive cases treated with the nail including 42 cases treated with the antegrade nail and 52 cases treated with the retrograde nail.

Patients who are in the national data opt-out, i.e., those who don't want to be contacted for research purposes will be excluded. Medical records of potential patients will be checked to ensure that deceased patients are not contacted. Patients will be sent a letter of invitation and a patient information sheet about the study and subsequently contacted 3-4 weeks later to answer any queries regarding the study. If the consent to participate, the investigator will document verbal consent and conduct a brief telephone interview and ask questions detailed in the visual analogue scale to assess pain and the Oxford hip/ Oxford knee score to assess hip/ knee function.

Furthermore, medical records of patients who consent will be reviewed and data collection will be performed by members of the clinical study team and stored on secure password protected computers accessible only to the study team. Data collected will include baseline demographics like age, sex, weight, height, patient comorbidities and medical history. Other information collected will include mechanism of injury, type of fracture, surgical procedure performed and duration, device (antegrade or retrograde nail) used. X-rays performed during the follow-up will be reviewed to identify if the fracture has healed and the time to union. Clinical records will be reviewed to assess if fracture has healed clinically.

Lastly, an untoward adverse events or complications during surgery and following surgery will be recorded. Any revision surgical procedure recorded will be recorded.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Zimmer natural nail - antegrade and retrograde nail

Primary outcome(s)
Time to fracture union is measured using radiographic assessment of complete healing on X-rays at clinical reviews

Key secondary outcome(s))
1. Occurrence of adverse events is measured using clinician-reported data from medical records at any time until patient discharge
2. Implant-related adverse events are measured using clinician assessment of causality from medical records at any time until patient discharge
3. Hip function is measured using the Oxford Hip Score questionnaire during the follow up call
4. Knee function is measured using the Oxford Knee Score questionnaire during the follow up call
5. Residual pain is measured using the Visual Analogue Scale during the follow up call

Completion date
31/01/2026

Eligibility

Key inclusion criteria
Patients having received the Antegrade Femoral Nail for temporary stabilization and fixation of femoral fractures and osteotomies or patients having received the Retrograde Femoral Nail for temporary stabilization and fixation of femoral fractures.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
94

Key exclusion criteria

1. Off-label use
2. Infection in bone or surrounding structures prior to surgery
3. A medullary canal obliterated by a previous fracture or tumor
4. Bone shaft having excessive bow or deformity
5. Lack of bone substance or bone quality, which makes stable seating of the implant impossible
6. All concomitant diseases that can impair the functioning and success of the implant
7. Insufficient blood circulation (peripheral vascular disease)
8. Skeletally immature patients (patients who have an open physis)
9. Patients who are registered in the national data opt-out

Date of first enrolment
10/03/2025

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Kent & Canterbury Hospital
Ethelbert Road
Canterbury
England
CT1 3NG

Sponsor information

Organisation
East Kent Hospitals University NHS Foundation Trust

ROR
https://ror.org/02dqqj223

Funder(s)

Funder type
Not defined

Funder Name
Zimmer Biomet

Alternative Name(s)
Zimmer Biomet Spine, Zimmer Biomet Biologics

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
Datasets generated during and/or analysed during the current study will be available upon request from Raman Thakur (raman.thakur@nhs.net)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	07/11/2024	26/11/2025	No	Yes
Protocol file	version 1.1	08/11/2024	26/11/2025	No	No