ISRCTN15076882 https://doi.org/10.1186/ISRCTN15076882

Post-market surveillance study of the ADAPTIS Total Ankle Replacement with EVERLAST polyethylene insert

Submission date
27/03/2025

Recruitment status
Recruiting

Registration date
01/04/2025

Overall study status
Ongoing

Last Edited
01/04/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
An ankle replacement procedure consists of replacing the worn-out joint surfaces of the ankle with metal and plastic components that are shaped to allow continued movement of the ankle. There are several different types of ankle replacement available. All current ankle replacements have limited durability, and developing systems with improved durability is important. INFINITY™ ankle implants are already routinely used in NHS hospitals. The INFINITY™ with ADAPTIS™ and EVERLAST™ ankle replacement system is a development of the INFINITY™ ankle implant. This new implant has been designed to attach to the bone better and to wear out more slowly, potentially providing a better outcome for patients. This study is being conducted to find out how the INFINITY™ with ADAPTIS™ implant performs and how well participants are doing after surgery. Participants in this study will be among the first to receive INFINITY™ with ADAPTIS™ and EVERLAST™ system in the hospital.

Who can participate?
Patients aged over 21 years who are on the waiting list for a total ankle replacement and their surgeon has made a separate clinical decision confirming that they are suitable to receive the INFINITY™ with ADAPTIS™ and EVERLAST™ Technology Total Ankle System for the total ankle replacement surgery.

What does the study involve?
Before surgery: After consenting for the study, the research team will collect information from the participant's medical notes, including x-rays. The team will also contact the participant at either their appointment, via email or telephone to complete some questionnaires.

Surgery and hospital stay: A surgeon will perform the surgery using the INFINITY™ with ADAPTIS™ and EVERLAST™ Technology Total Ankle System. The care received in the hospital will be the same as standard care. The research team will collect information from medical notes about the surgery.

After surgery: After surgery, participants will be required to attend clinical appointments and receive additional x-rays as part of the enhanced follow-up process for up to 5 years.

• Outpatient appointments: First follow-up visit will be at 6 weeks post-surgery. Participants will be required to attend outpatient appointments and undergo x-rays at 6 months, 1 year, 2 years and 5 years post-operatively. Teams will collect information on any issues.

• Questionnaires: Participants will be asked to complete questionnaires at 6 months, 1 year, 2 years and 5 years post-operatively. These can be completed at a face-to-face appointment, over the telephone or via email.

What are the possible benefits and risks of participating?
It is hoped that the INFINITY™ with ADAPTIS™ and EVERLAST™ Technology Total Ankle System will offer:
1. Bony integration of the metallic components
2. Reduced pain
3. Restored alignment
4. Replacement of flexion and extension movement in the ankle

The potential benefits relating to a total ankle replacement in general include:
1. Pain reduction
2. Increased function
3. Improved quality of life

This study may help us to better treat future patients who need total ankle replacement surgery and inform future research.

Any surgery carries potential risks, including the surgery as part of this study. The potential risks relating to a total ankle replacement in general include:

1. Aseptic loosening of the prosthesis
2. Infection
3. Deep venous thrombosis
4. Post-operative pain
5. Heterotopic ossification
6. Fracture of the prosthesis
7. Fracture of the bone
8. Loss of muscle force
9. Nerve and vessel injury
10. Wound healing problems
11. Implant failure
12. Medical complications
13. Death

The evidence from testing the INFINITY™ with ADAPTIS™ and EVERLAST™ Technology Total Ankle System tells us that the risks are unlikely to be higher than the alternative options.

For women, the surgeon must be aware if they become pregnant before/after their surgery, as there could be additional risks to them or their foetus. If they become pregnant after surgery, the study team will continue to keep them in the study and follow-up, however, they will not expose them to additional radiographs during maternity.

Participants will have an x-ray of the ankle taken before the surgery (within 12 months prior to surgery), and at 6 months, 1 year, 2 years and 5 years post-operatively. As a newer implant was chosen as part of a routine treatment, participants will be monitored more closely, and so it is possible they may get slightly more X-rays than if they didn't take part, however, any difference in the schedule will be small.

X-rays use ionising radiation. Ionising radiation may cause cancer many years or decades after exposure. Everyone is at risk of developing cancer during their lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during their lifetime. Taking part in this study will add only a very small chance of this happening.

Where is the study run from?
North Tyneside General Hospital, UK

When is the study starting and how long is it expected to run for?
December 2023 to April 2031. Participants will be followed up for up to 5 years after ankle surgery.

Who is funding the study?
Stryker European Operations Limited

Who is the main contact?
stees.ukadaptisstudy@nhs.net

Contact information

Type(s)
Public, Scientific

Contact name
Mr David Townshend

ORCID ID
http://orcid.org/0000-0002-1384-4582

Contact details
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH
+44 (0)1912934021
David.townshend@nhct.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
338603

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 61149

Study information

Scientific Title
INFINITY™ with ADAPTIS™ and EVERLAST™ technology total ankle replacement follow-up

Acronym
UK ADAPTIS™ Study

Study objectives
There are several different types of ankle replacement available. Infinity ankle implants are already routinely used in NHS hospitals. The INFINITY™ with ADAPTIS™ and EVERLAST™ ankle replacement system is a development of the Infinity ankle implant, designed to attach to the bone better and to wear out more slowly.

The hypothesis of the UK ADAPTIS™ Study is to evaluate the performance and function of the newly introduced INFINITY™ with ADAPTIS™ and EVERLAST™ technology Total Ankle System for total ankle replacement (TAR) or arthroplasty (TAA) and EVERLAST™ Poly Insert that modernises and streamlines Stryker's TAA/TAR portfolio.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/03/2024, Yorkshire & The Humber – South Yorkshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8021, (0) 2071048075; southyorks.rec@hra.nhs.uk), ref: 24/YH/0053

Study design
Observational interventional case series

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital, Internet/virtual, Medical and other records, Telephone

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

INFINITY™ with ADAPTIS™ and EVERLAST™ Technology with Poly Insert for patients requiring primary total ankle replacement/arthroplasty (TAR/TAA) across up to 10 UK NHS Hospital Trusts regularly performing TAA/TAR.

Interventions

Study design

A prospective multi-centre observational cohort series of INFINITY™ with ADAPTIS™ and EVERLAST™ Technology with Poly Insert for patients requiring primary total ankle replacement /arthroplasty (TAR/TAA) across up to 10 UK NHS Hospital Trusts regularly performing TAA/TAR.

The study will have a minimum 12-month recruitment period and up to 5 years post-operative follow-up (6 weeks, 6 months,1 year, 2 years, and 5 years).

Intervention and indication

INFINITY™ with ADAPTIS™ and EVERLAST™ technology with Poly Insert for patients requiring primary TAA/TAR.

It is intended to give a patient limited mobility by reducing pain, restoring alignment, and replacing flexion and extension movement in the ankle joint with benefit for patients with ankle joints damaged by severe rheumatoid, posttraumatic, or degenerative arthritis or a failed previous ankle surgery.

Screening and recruitment

Patients will primarily be screened from theatre lists of patients waiting for a TAA/TAR and are eligible to receive the INFINITY™ with ADAPTIS™ and EVERLAST™ technology Total Ankle System for TAA/TAR as part of their routine care. Patients may also be screened from orthopaedic outpatient clinics where patients have been referred through standard practice.

Members of the healthcare team or a delegated member of the research delivery team will screen for eligible patients and have their eligibility confirmed by their treating clinician.

All patients who have been screened will need an eligibility form completed on REDCap. For those who are eligible, a contact details form will also need to be completed, and they will be contacted by a delegated member of the research delivery team. They will be provided a patient information sheet (PIS) in person, via their email or post, depending on patient preference.

If a patient is interested, consent will be collected (a) electronically via REDCap (in person or via a link sent); (b) written consent (in person or via post) and uploaded to REDCap; (c) verbal consent, which will be documented on REDCap – this will need to be followed up by either electronic or written consent.

Each site will keep an electronic screening log, documenting the date of screening, results of screening and the primary reason for excluding a patient or the reason a patient has decided not to participate, as available. The screening log will be held on the secure database REDCap as hosted by the study management team at South Tees Hospitals NHS Foundation Trust.

Data collection
The study data will be collected and managed using REDCap electronic data capture tools, hosted at South Tees Hospital NHS Foundation Trust. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; and (3) automated export procedures for seamless data downloads to common statistical packages; (4) procedures for data integration and interoperability with external sources.

a. Screening and eligibility
b. Consent (valid for 12 months)
c. Pre-operative clinical history (including radiographs) and PROMs
d. Intra-operative evaluation
e. Post-operative clinical history (including radiographs) and PROMs (6 months +/- 5 weeks, 1 year +/- 6 weeks, 2 years +/- 3 months, and 5 years +/- 6 months). Clinical history only at 6 weeks post-op +/- 2 weeks.
f. Withdrawal or discontinuation
g. Adverse events

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
INFINITY™ with ADAPTIS™ and EVERLAST™ technology with Poly Insert

Primary outcome measure
1. Functional status measured using the Manchester-Oxford Foot Questionnaire (MOXFQ) at 2 years post-operative
2. Device survivorship, defined as the removal or exchange of one or more of the components (excluding incidental polyethylene exchange for infection) at 2 years

Secondary outcome measures
The following secondary outcome measures will be measured using data collected in study records:
1. Survivorship, defined as the removal or exchange of one or more of the components (excluding incidental polyethylene exchange for infection), at 2 years, 5 years and post-operative.
2. Revision of any components (excluding incidental polyethelene exchange for infection) by the end of the study
3. Re-operation without revision by the end of the study
4. Type and frequency of adverse events (AEs), specifically operative and device-related AEs and Serious AEs (SAEs) by the end of the study
5. Functional status, pain and disability (MOXFQ & AOS) and health-related quality of life (EQ5D-5L) at 6 months, 1 year, 2 years, and 5 years post-operative.

Overall study start date

01/12/2023

Completion date
01/04/2031

Eligibility

Key inclusion criteria
1. Male or non-pregnant female over the age of 21 years with a diagnosis of end-stage ankle arthritis and requiring primary TAA/TAR and is suitable for the use of the ADAPTIS TAA/TAR.
2. Patients who are physically and mentally willing and able to comply with the post-operative follow-ups and an appropriate rehabilitation schedule.
3. The patient can understand and provide written consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
21 Years

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 179

Key exclusion criteria
1. Patients with previous ankle arthrodesis or Patients who require revision of previously implanted TAA/TAR.
2. Any patients presenting with clinically relevant conditions prior to implantation that would contraindicate the implantation of a TAA/TAR.

Date of first enrolment
18/04/2024

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
United Kingdom
HA7 4LP

Study participating centre
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Gobowen
Oswestry
United Kingdom
SY10 7AG

Study participating centre
NIHR Nottingham Biomedical Research Centre
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft

Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Royal Albert Edward Infirmary
Wigan Lane
Wigan
United Kingdom
WN1 2NN

Study participating centre
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Torbay Hospital
Newton Road

Torquay
United Kingdom
TQ2 7AA

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details
North Tyneside General Hospital, Rake Lane
North Shields
England
United Kingdom
NE29 8NH
+44 (0)1912934087
Peta.Heslop@nhct.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.northumbria.nhs.uk/

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Industry

Funder Name
Stryker

Alternative Name(s)
Stryker Corporation

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
It is anticipated that a publication of the study results will be compiled and submitted to a peer-reviewed journal. The CI of the study will have the responsibility of being the primary author of such publications.

Intention to publish date
01/04/2032

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

Information collected for the study will be accessed to analyse the results. The identities of the participants in this study will remain strictly confidential. Details such as name, date of birth and address will not be shared.

Analysis of results will be organised by the CI and the study management team. A detailed Statistical Analysis Plan will be agreed with an expert statistician before conducting any analyses. The analyses will be mainly descriptive. Continuous data will be summarised using means and standard deviations (or median, interquartile range, minimum and maximum as appropriate). Categorical data will be summarised using counts and percentages. Graphs will be produced to display trajectories in outcomes over time. Linear or logistic regression models (as appropriate depending on the outcome) will be used to evaluate the influence of patient, clinical and surgical factors on outcomes.

AEs and SAEs will be summarised descriptively and using graphs by whether they are operative or device-related.

IPD sharing plan summary
Data sharing statement to be made available at a later date