ISRCTN57876689 https://doi.org/10.1186/ISRCTN57876689

A prospective clinical evaluation of the Trident II 3D printed acetabular component in total hip replacement patients

Submission date 23/08/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/08/2023	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 08/10/2025	**Condition category** Surgery	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

The hip is a ball and socket joint. The ball is at the top of your thigh bone, and the socket is part of your pelvic bone. In a total hip replacement (arthroplasty), both the ball and the socket will be replaced. The Trident® II acetabular component is a new implant that will be used to replace the socket of the hip aiming to offer patients a better range of movement, lower the risk of dislocation and a more stable joint. Trident implants are routinely used in South Tees hospital in patients who require a hip replacement. It is important to find out how the new Trident® II implant performs and how well patients are doing after surgery.

Who can participate?

People aged 40 to 75 who have issues with their hip joints like arthritis or injuries. Thesepeople should be willing and able to follow the doctor's orders after getting a new hip joint, and they should be okay with the idea of rehabilitation (exercise to get better). They must also be mentally ready and understand what they're signing up for. It's important that they don't have any major health problems that could interfere with the results.

What does the study involve?

Before surgery: This study will take place at South Tees Hospital NHS Foundation Trust, where their surgery and outpatient appointments would also take place. Eligible participants will be asked to read and understand a Participant Information Sheet and will be asked to sign an Informed Consent Form for the study. The research team will collect information from the participants medical notes, including x-rays. The team will also contact the participant via email or telephone to complete some questionnaires.

Surgery and hospital stay: The surgeon will perform the surgery using the Trident® II implant. The care the participant will receive in hospital will be the same as standard care. The research team will collect information from the participants medical notes about the surgery and hospital stay. X-rays will be taken before the participant leaves the hospital.

After surgery: The participant 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. (1) Outpatient appointments: Participants will be required to attend outpatient appointments at 6-12 weeks, 1 year. The team will collect information on any issues and X-rays will also be taken during the 1-year appointment. (2) Questionnaires: Participants will be asked to complete questionnaires (at the appointment, over the telephone or via email) at 6-12 weeks, 1 year, and 5 years.

What are the possible benefits and risks of participating?
Benefits of Trident II implant: A better range of movement, a lower risk of dislocation, a more stable joint compared to the standard component.
Benefits of a total hip replacement in general: Pain reduction, increased function, improved quality of life.
Risks of Trident II implant: The evidence from testing the Trident II acetabular component tells us that the risks are unlikely to be higher than the alternative options.

Risks of a total hip replacement in general: Failure of the implant due to a non-infection related cause (aseptic loosening of the prosthesis), infection, blood clot (deep vein thrombosis), post-operative pain, new bone in the soft tissues (heterotopic ossification), fracture of the implant or bone, loss of muscle function, dislocation, medical complications or death, leg length discrepancy, nerve and vessel injury.

Where is the study run from?
South Tees Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2022 to October 2030

Who is funding the study?
Stryker (USA)

Who is the main contact?
Dr Lucksy Kottam, lucksy.kottam@nhs.net

Contact information

Type(s)
Scientific

Contact name
Miss Natalie Clark

ORCID ID
https://orcid.org/0000-0002-9462-4425

Contact details
Academic Centre for Surgery
James Cook University Hospital
Middlesbrough
United Kingdom

TS4 3BW
+44 1642 835764
natalie.clark17@nhs.net

Type(s)
Scientific

Contact name
Dr Lucksy Kottam

ORCID ID
https://orcid.org/0000-0002-7976-2416

Contact details
Academic Centre for Surgery
James Cook University Hospital
Middlesbrough
United Kingdom
TS4 3BW
+44 1642 854814
lucksy.kottam@nhs.net

Type(s)
Principal investigator

Contact name
Mr Simon Jameson

Contact details
South Tees Hospitals NHS Foundation Trust
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW
+44 1642850850
simonjameson@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
276445

Protocol serial number
CPMS 52086, H-I-121, IRAS 276445

Study information

Scientific Title
Performance and function of the Trident® II 3D printed acetabular component

Acronym
Trident® II 3D - South Tees

Study objectives
The risks of revision, re-operation and complications for a Trident II 3D printed acetabular component will be equivalent to other types of hybrid total hip replacement reported in the literature. The Trident II 3D printed acetabular component will demonstrate equivalent function and risk of dislocation compared to other types of hybrid total hip replacement reported in the literature.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/03/2022, South West - Central Bristol Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 2071048029; centralbristol.rec@hra.nhs.uk), ref: 22/SW/0024

Study design
Non-randomised cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Total hip arthroplasty

Interventions
Current interventions as of 08/10/2025:
Participants will undergo hip replacement surgery with a Trident® II 3D printed acetabular component.

Patients will be included in the study for up to 6 years in total. Approximately a 12-month enrollment period, plus up to 5 years post-operative follow-up for each patient (6/12 weeks, 1 year, and 5 years).

Previous Interventions:
Participants will undergo hip replacement surgery with a Trident® II 3D printed acetabular component.

Patients will be included in the study for up to 11 years in total. Approximately a 12-month enrollment period, plus up to 10 years post-operative follow-up for each patient (6/12 weeks, 1 year, 3 years, 5 years, 7 years, 10 years).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Patient reported outcome measures (PROMs) assessing symptoms and functional limitations measured using the Oxford Hip Score (OHS) at baseline and at 1 year post-operatively
2. Device survivorship measured by clinical assessment (rates of re-operation and revision, including any adverse events) at 1 year post-operatively

Key secondary outcome(s))
Current secondary outcome measures as of 08/10/2025:
1. PROMs assessing symptoms and functional limitations measured using the Oxford Hip Score (OHS): pre-operative and 6-12 weeks, 1 year, and 5 years post-operative
2. PROMs assessing awareness of artificial joint in everyday life measured using the Forgotten Joint Score (FJS): pre-operative and 6-12 weeks, 1 year, and 5 years post-operative
3. PROMs assessing health outcome and quality of life measured using the EQ5D5L: pre-operative and 6-12 weeks, 1 year, and 5 years post-operative
4. Device survivorship measured by clinical assessment (rates of re-operation and revision, including any adverse events) prior to discharge (PTD), 6-12 weeks, 1 year, and 5 years post-operative. Radiographic assessment will also be collected as part of device survivorship and national recommendations of the British Orthopaedic Association (BOA) for follow-up of a new implant, collected: pre-operative, PTD, 1 year post-operative

Previous secondary outcome measures:
1. PROMs assessing symptoms and functional limitations measured using the Oxford Hip Score (OHS): pre-operative and 6-12 weeks, 1 year, 3 years, 5 years, 7 years and 10 years post-operative
2. PROMs assessing awareness of artificial joint in everyday life measured using the Forgotten Joint Score (FJS): pre-operative and 6-12 weeks, 1 year, 3 years, 5 years, 7 years and 10 years post-operative
3. PROMs assessing health outcome and quality of life measured using the EQ5D5L: pre-operative and 6-12 weeks, 1 year, 3 years, 5 years, 7 years and 10 years post-operative
4. Device survivorship measured by clinical assessment (rates of re-operation and revision, including any adverse events) prior to discharge (PTD), 6-12 weeks, 1 year, 5 years and 10 years post-operative. Radiographic assessment will also be collected as part of device survivorship and national recommendations of the British Orthopaedic Association (BOA) for follow-up of a new implant, collected: pre-operative, PTD, 1 year, 5 years and 10 years post-operative

Completion date
31/10/2030

Eligibility

Key inclusion criteria
1. Male or non-pregnant female between 40 and 75 years of age with a diagnosis of osteoarthritis (OA), avascular necrosis (AVN) or post-traumatic arthritis (PTA) and requiring primary THA and is suitable for the use for the uncemented Trident II acetabular component, in combination with any Stryker liner and any compatible femoral head and stem.
2. Patients who are physically and mentally willing and able to comply with the post-operative follow-ups and an appropriate rehabilitation schedule.
3. Patient is able to understand and provide written consent.
4. Patients with no clinically relevant disorders undergoing THA.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
75 years

Sex
All

Total final enrolment
106

Key exclusion criteria
1. Patients deemed by the treating surgeon to be unable to comply with the prescribed post-operative routine and follow-up evaluation schedule.
2. Patients with rheumatoid arthritic hip as well as history of acetabular or femoral osteotomy.
3. Patients who have had a THA on the contra-lateral side within last 6 months.
4. Patients who are likely to need further lower limb joint replacement for another joint within one year.
5. Female patients between the ages of 40 and 75 years that are pregnant or planning a pregnancy up to 1 year during which they would have received the implant.
6. Patients who require revision of previously implanted THA.
7. Patients with active or suspected infection, requiring treatment.
8. Patients with active malignancy.
9. Patients diagnosed with systemic disease that would affect patient's welfare or overall outcome of the study (severe osteoporosis, Paget's Disease, renal osteodystrophy) or is immunologically suppressed, or receiving steroids in excess of physiologic dose.
10. Patients with a neuromuscular or neurosensory deficit which would limit the ability to assess the performance of the device or the patient has a neurological deficit which interferes with the patient's ability to limit weight bearing or places an extreme load on the implant during the healing period.
11. Patients with systemic or metabolic disorders leading to progressive bone deterioration (such as rickets, osteomalacia, osteogenesis, imperfecta, marble bone disease, (osteopetrosis), Paget disease of bone and fibrous dysplasia).
12. Patients with other concurrent illnesses which are likely to affect their outcome such as sickle cell anaemia, systemic lupus erythematosus, psoriasis or renal disease requiring dialysis.
13. Patients with a body mass index (BMI), $kg/m^2 > 40$. Obese patients where obesity is severe enough to affect patient's ability to perform activities of daily living.
14. Is the patient involved in a research study that, in the opinion of the PI, would affect their continued participation in the previous study and/or would affect the current study intervention and/or their treatment outcomes.

Date of first enrolment
09/05/2022

Date of final enrolment
01/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
James Cook University Hospital
South Tees Hospitals NHS Foundation Trust
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Industry

Funder Name
Stryker

Alternative Name(s)
Stryker Corporation, Orthopedic Frame Company

Funding Body Type

Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2	09/03/2022	24/08/2023	No	Yes