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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 09/09/2024	**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 10 years. (1) Outpatient appointments: Participants will be required to attend outpatient appointments at 6-12 weeks, 1 year, 5 years and 10 years. The team will collect information on any issues and x-rays will also be taken during the 1 year, 5 year and 10 year appointments. (2) Questionnaires: Participants will be asked to complete questionnaires (at the appointment, over telephone or via email) at 6-12 weeks, 1 years, 3 years, 5 years, 7 years and 10 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 July 2034

Who is funding the study?
Stryker (USA)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
276445

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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

Interventions
Participants will undergo hip replacement surgery with 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 measure
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

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

Overall study start date
15/03/2022

Completion date
01/07/2034

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

Age group

Adult

Lower age limit
40 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

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
England

United Kingdom

Study participating centre
James Cook University Hospital
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Sponsor type
Hospital/treatment centre

Website
http://southtees.nhs.uk/

ROR
https://ror.org/02js17r36

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 high-impact peer-reviewed journal. There will be an interim analysis at 50 patients at 6-12 weeks post-operative, with further analysis of all patients at 1 year post-operative. We expect the first publication to be following the 3 year post-operative follow-up analysis.

Intention to publish date
31/07/2026

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