ISRCTN60834248 https://doi.org/10.1186/ISRCTN60834248

The Fixed Bearing Lateral Stabilised DJO 3D Knee™ versus the Finsbury Medial Rotation Knee™ System versus the Stryker Triathlon® knee in primary total knee replacement for osteoarthritis and rheumatoid arthritis

Submission date	Recruitment status	[X] Prospectively registered
30/06/2011	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
01/08/2011	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
12/02/2018	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Arthritis is a common condition that causes pain and inflammation in the joints. The two most common types of arthritis are rheumatoid arthritis (RA) and osteoarthritis (OA). Osteoarthritis (OA) is the most common type, affecting millions of people worldwide. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, which can cause stiffness, pain, and a reduction in the range of movement. Rheumatoid arthritis (RA) is a disease of the immune system, known as an autoimmune disease. This happens when the cells in the immune system do not behave as they should do, and start to attack healthy joints. In both OA and RA, the most common joint to be affected is the knee. In severe cases, surgery may be the only treatment that can provide patients with relief. A total knee arthroplasty (TKA), also known as a total knee replacement, is recommended if the pain in the knee is so severe that it is causing disability. In the operation, diseased cartilage and bone is removed from the surface of the knee joint and replaced with a man-made surface of metal or plastic (prosthesis). The “new” joint is more stable and helps a person to recover their range of motion (ROM), the amount that the joint can be bent (flexion) and straightened (extension). The most successful operations are able to give patients a greater ROM, and the design of the prosthesis may play an important part in this. The aim of this study is to find out whether newer, more flexible designs of prosthesis are able to give people a better ROM than traditional designs of prosthesis.

Who can participate?
Adults who are having a total knee replacement due to osteoarthritis or rheumatoid arthritis.

What does the study involve?
Participants are randomly allocated into three groups, each of which receiving a different design of knee prosthesis: the Lateral Stabilised 3D Knee™, the Medial Rotation Knee™ or the

Triathlon® Knee. Six weeks after the operation, participants complete a ROM test, designed to find out the degree of flexion and extension of the knee joint. This test is repeated six months, one year and two years after the operation.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Orthopaedics and Trauma, University College London Hospitals (UK)

When is the study starting and how long is it expected to run for?
August 2011 to September 2019

Who is funding the study?
DJO Surgical (USA)

Who is the main contact?
Professor Fares Haddad

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.5

Study information

Scientific Title

A prospective randomised controlled study of the Fixed Bearing Lateral Stabilised DJO 3D Knee™ versus the Finsbury Medial Rotation Knee™ System versus the Stryker Triathlon® knee in primary total knee replacement for osteoarthritis and rheumatoid arthritis

Study objectives
The null hypothesis is that there is no difference in range of motion (ROM) at six months post operative, between the three different designs of prosthesis.

On the basis of the 3D knee prosthesis design, primary study hypotheses are:
1. Greater range of motion through posterior femoral roll back and maximum posterior condyler offset
2. Intrinsic stability will achieve functional strength comparable to other intrinsically stable designs

The secondary study hypothesis is:
Greater patient satisfaction as a result of the above

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London City & East, 12/03/2012, ref: 11/LO/1390

Study design
Single centre prospective partially blinded randomised controlled parallel three group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Osteoarthritis or rheumatoid arthritis affecting the knee

Interventions
The study is a partially blinded, randomised controlled trial of the three knee implants. Adult patients requiring a primary knee replacement for osteoarthritis or rheumatoid arthritis will be randomised to one of the implants.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Knee range of motion measured in degrees, at six months post-operative
2. The study has been powered to detect a difference of 10 degrees between any two implants
3. The primary outcome will be analysed by linear regression with study group as the explanatory variable

Secondary outcome measures
1. Validated Health Related Quality of Life measures
1.1. American Knee Society Score
1.2. Oxford Knee Score
1.3. Western Ontario and McMasters University Osteoarthitis (WOMAC)
1.4. SF-36 Health Survey
1.5. UCLH functional score
2. Radiological analysis
3. Survivorship information
4. Complication rates
5. Knee ROM
Measured at six months post-operative

Overall study start date
01/08/2011

Completion date
30/09/2019

Eligibility

Key inclusion criteria
1. The patient and surgeon must agree that total knee replacement (TKR) is necessary
2. The patient must be fit for TKR in the opinion of the Investigator
3. The patient must be 18 years of age or older at the time of recruitment
4. The inclusion of minors would introduce an extremely rare subset of TKR patients in which the surgeons choice of implant is desirable
5. The patient must be able to fully understand the study and must therefore be fluent in English. If they are not fluent in English, a translator will be used
6. The patient must be a permanent resident in an area accessible to the study site
7. The indication for TKR must be osteoarthritis or rheumatoid arthritis
8. This must be the patients first TKR

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Patient has clinical contra-indications for use of the 3D, MRK or Triathlon Knee systems in the opinion of the Investigator
2. Underlying neuromuscular/neurovascular problems
3. The patient already has a TKR on the contralateral side
4. Patient lacks the capacity to consent, is unwilling or unable to sign the consent form
5. Patient aged <18 years at time of consenting to study

Date of first enrolment
01/08/2011

Date of final enrolment
25/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Orthopaedics and Trauma
University College London Hospitals
Ground Floor North
250 Euston Road
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Sponsor information

Organisation
Joint UCL/UCLH/Royal Free Biomedical Research Unit (UK)

Sponsor details

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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
DJO Surgical (USA)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal in 2019.

Intention to publish date
31/12/2019

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.

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