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A clinical study to assess whether there is a difference in outcomes in patients receiving either the PFC or the Attune knee replacement

Submission date
04/10/2020

Recruitment status
No longer recruiting

Registration date
06/10/2020

Overall study status
Completed

Last Edited
07/01/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Total knee replacement (arthroplasty) is usually a successful procedure with excellent outcomes although 15% of patients report they are dissatisfied. Design differences between replacement knee parts (prostheses) continue to be developed in an effort to improve these outcomes. The aim of this study is to evaluate the effect of these new design features on the outcomes following total knee arthroplasty.

Who can participate?
Patients aged 22 to 90 years old, with osteoarthritis of the knee requiring replacement

What does the study involve?
Participants will be randomly allocated to undergo a total knee replacement with either the DePuy Synthes ATTUNETM or the DePuy Synthes PFC SigmaTM cruciate-retaining systems. Patients will be followed up for 1 year.

What are the possible benefits and risks of participating?
The possible benefits include active participation in a trial to improve patient outcomes, and playing an important part in improving patient outcomes whilst not compromising their own outcome.
The new implant may not necessarily improve outcomes, but there are several studies highlighting that the newer implant has at least equivalent outcomes and is not inferior which maintains patient safety. The longer-term outcomes are yet unknown - i.e. the longevity of implant, and the need for revision at an earlier stage.

Where is the study run from?
Wrightington Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2014 to August 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Sunil Panchani
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
160047

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 160047

Study information

Scientific Title
Early functional outcomes after evolutionary total knee arthroplasty: a randomized controlled trial

Study objectives
This study investigates whether or not there is a difference between the PFC or the Attune Total Knee replacement systems in terms of functional and clinical outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/11/2014, NRES Committee North West - Greater Manchester South (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8063; gmsouth.rec@hra.nhs.uk), REC ref: 14/NW/1330

Study design
Single (patient) blinded single centre randomized controlled 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Osteoarthritis of knee

Interventions
The study is designed as a single-blinded randomized controlled trial with patients blinded to their treatment arm. Subjects will remain blinded as to their treatment arm for the duration of the trial period which will be 1 year for each subject. The patient population will comprise patients being referred to or currently under review for symptomatic knee osteoarthritis at Wrightington Hospital, United Kingdom.

Patients will be primarily recruited and consented during the clinic consultation. Enrolment and consent to the trial will only be performed by researchers with Good Clinical Practice (GCP) certification. Consent forms and patient information sheets have been devised using departmental guidance and protocols.

Procedure
Patients undergo a total knee replacement with either the DePuy Synthes ATTUNETM or the DePuy Synthes PFC SigmaTM cruciate-retaining system

Data collection
Both demographic and clinical data will be recorded throughout the trial period. Demographic data will include age, sex, height, weight, body mass index as well as co-morbidities. Clinical data will include implant sizes, wound closure methods, tourniquet time, ASA grade, Hospital Length of Stay, Pre and post-operative Haemoglobin and complications including but not limited to

infection, deep vein thrombosis and further surgery to the operated or non operated limb within the trial period for any reason will be recorded.

Clinical and Functional Outcome measures
The outcomes of interest comprise general and disease-specific patient-reported outcome measures (PROMs). Disease-specific scores include the Oxford Knee Score (OKS)7, the Oxford Knee Score Activity and Participation Questionnaire (OKS-APQ)8 and the Patient Knee Implant Performance score (PKIP)9. The SF-3610 and EQ5D – 5L11 will also be completed as generic health measures.
The pre- and post-operative range of movement (ROM) as measured with a goniometer will also be assessed together with Visual Analogue Pain Scores (VAS).

Trial packs comprising a pre-operative pack, a 6-week post-operative pack, a 12-week post-operative pack and a 52-week post-operative pack will be devised comprising the relevant outcome measures to allow ease of completion for the subjects.

Randomization
Patients will be randomized using sealed envelopes based on lists prepared in advance of the first patient being randomised. Randomisation lists shall be produced by the trial statistician via randomly permuted blocks using the 'ralloc' command within the statistical package Stata R. No stratification factors are to be included in the study.

The primary endpoint is the difference between pre-surgery and 6 weeks, 3 months and 1-year measurements of the Oxford Knee Score.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
PFC and ATTUNE Total Knee Replacement systems - DePuy Synthes

Primary outcome measure
Knee function measured using the Oxford Knee Score at baseline, 6 weeks, 3 months and 1 year

Secondary outcome measures
1. Knee function measured using the OKS-APQ Questionnaire at baseline, 6 weeks, 3 months and 1 year
2. Knee function measured using the PKIP Questionnaire at baseline, 6 weeks, 3 months and 1 year
3. General health measured using the SF-36 Questionnaire at baseline and 1 year
4. Quality of life measured using the EQ5D-5L Questionnaire at baseline, 6 weeks, 3 months and 1 year
5. Pain measured using VAS Questionnaire at baseline, 6 weeks, 3 months and 1 year
6. Range of movement measured using a Goniometer at baseline, 6 weeks, 3 months and 1 year

Overall study start date
01/05/2014

Completion date
01/08/2017

Eligibility

Key inclusion criteria
1. 22 to 90 years old inclusive
2. A diagnosis of non-inflammatory osteoarthritis of the knee
3. Primary varus osteoarthritic deformity
4. Stable collateral ligaments at the time of pre-operative clinical examination
5. Patient is a candidate for routine primary knee arthroplasty (cruciate retaining) in line with manufacturer guidelines
6. Subject is able to give consent to the procedure

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Total final enrolment
150

Key exclusion criteria
1. A patient with a diagnosis of inflammatory osteoarthritis
2. Severe bone defects or deformity which will require augmentation with bone graft or augmented prosthesis or a constrained device
3. Valgus osteoarthritis
4. Previous patellectomy
5. Patient has a contralateral TKR which is a PFCTM or ATTUNETM implant
6. Patient has a poorly functioning or symptomatic contra-or ipsilateral total hip replacement
7. Previous lower limb amputation on either limb
8. Previous fractures, osteotomy or surgery to the knee which required metal implantation and /or ligament reconstruction
9. Neurogenic cause for arthritis in the knee or associated neurological symptoms in lower limb referred from spine

Date of first enrolment
01/12/2014

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wrightington Hospital
Appley Bridge
Hall Lane
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Sponsor information

Organisation
Wrightington Hospital

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Sponsor type
Hospital/treatment centre

Website
http://www.wwl.nhs.uk/hospitals/wrightington/default.aspx

ROR
https://ror.org/00y112q62

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal
JBJS - article
BOA, BASK - International Presentations

Intention to publish date
01/04/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. The data is stored in a secure password-protected file on a Hospital secured drive and only the research team have access to this.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/08/2015	06/10/2020	Yes	No
Results article		28/07/2021	07/01/2022	Yes	No
HRA research summary			28/06/2023	No	No