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Functional outcome of the P.F.C. Sigma® RP-F knee system and the P.F.C. Sigma® knee system

Submission date	Recruitment status	[X] Prospectively registered
24/07/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/04/2022	Musculoskeletal Diseases	

Plain English summary of protocol
Background and study aims
Knee osteoarthritis is a condition where the cartilage inside the knee joint is worn away, leading to the bones rubbing against each other and becoming damaged. In knee replacement surgery, the damaged knee joint is removed and replaced with an implant. Different knee implants are available. The aim of this study is to find out whether the P.F.C.®Sigma RP-F knee system provides patients with a higher range of motion than the P.F.C.®Sigma knee system.

Who can participate?
Patients aged 18 and over with knee osteoarthritis who require knee replacement surgery

What does the study involve?
Participants are randomly allocated to undergo knee replacement surgery with either a P.F.C. Sigma® RP-F or a P.F.C. Sigma® knee system. Range of motion is measured at 12 months.

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

Where is the study run from?
James Cook University Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2008 to March 2019

Who is funding the study?
South Tees Hospitals NHS Trust (UK)

Who is the main contact?
Mr Anthony Hui

Contact information

Type(s)

Scientific

Contact name
Mr Anthony Hui

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Additional identifiers

Protocol serial number
MTO 001

Study information

Scientific Title
Functional outcome of the P.F.C. Sigma® RP-F knee system and the P.F.C. Sigma® knee system: a prospective, randomised controlled trial

Acronym
RP-F trial

Study objectives
The primary objective of this clinical trial is to test the hypothesis that the P.F.C.®Sigma RP-F knee system can deliver a higher post-operative Range Of Motion (ROM) than the P.F.C.®Sigma knee system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
County Durham & Tees Valley 1 Research Ethics Committee, 30/08/2007, ref: 07/H0905/67

Study design
Prospective randomised controlled single-centre trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Eligible subjects will be randomised to primary total knee replacement with a P.F.C. Sigma® RP-F or a P.F.C. Sigma® knee system.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Measurement of the difference in the mean ROM between participants receiving a primary total knee replacement with either the P.F.C. Sigma® RP-F or the P.F.C. Sigma® knee system at 12 months.

Key secondary outcome(s))
Comparative evaluation of any post-operative variation between participants receiving a primary total knee replacement with either the P.F.C. Sigma® RP-F or the P.F.C. Sigma® knee system in change from baseline at each post operative time point (3, 12, 60 and 120 months) in terms of:
1. Functional recovery using the Oxford Knee Score
2. Quality of life assessed by the Short Form-12 (SF-12v2) questionnaire
3. American Knee Society Score
4. Survivorship analysis of the two groups at 60 and 120 months post-operatively

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Male or female subjects, aged 18 years and older.
2. Subjects who are able to give voluntary, written informed consent to participate in this investigation and from whom consent has been obtained.
3. Subjects who, in the opinion of the Investigator, are able to understand this investigation, co-operate with the investigational procedures and are willing to return to the hospital for all the required post-operative follow-ups.
4. Subjects who present with idiopathic or posttraumatic osteoarthritis that in the opinion of the clinical investigator requires a primary total knee arthroplasty and who are considered suitable for treatment with P.F.C. Sigma® RP-F and P.F.C. Sigma® knee systems.
5. Subjects, who in the opinion of the Clinical Investigator, are considered to be suitable for treatment with both investigational devices, according to the indications specified in the package insert leaflet.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Subjects who, in the opinion of the Investigator, have an existing condition that would compromise their participation and follow-up in this study.
2. Subjects with a Body Mass Index (BMI) >35.
3. Subjects with a known history of poor compliance to medical treatment.
4. Women who are pregnant.
5. Subjects who are known drug or alcohol abusers or with psychological disorders that could affect follow-up care or treatment outcomes.
6. Subjects involved in Medical-Legal claims.
7. Intra-operative use of augmentation devices.
8. Intra-operative decision to resurface the patella based on clinical indication.
9. Revision of an existing knee implant.

Date of first enrolment
01/03/2008

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
James Cook University Hospital
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
South Tees Hospitals NHS Trust (UK)

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
South Tees Hospitals NHS Trust (UK) - Division of Trauma

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2010	13/04/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes