

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

<b>Submission date</b> 24/07/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/04/2022	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## 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

**Contact details**

James Cook University Hospital  
Division of Trauma  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

**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, cooperate 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?
<a href="#">Results article</a>		01/03/2010	13/04/2022	Yes	No