

Total knee arthroplasty versus patellofemoral arthroplasty in patients with severe arthritis of the patellofemoral joint

Submission date
20/08/2009

Recruitment status
No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date
02/09/2009

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
28/07/2023

Condition category
Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

AP1170

Study information

Scientific Title

The Warwick patellofemoral arthroplasty trial: a randomised clinical trial of total knee arthroplasty versus patellofemoral arthroplasty in patients with severe arthritis of the patellofemoral joint

Study objectives

The objective of the study is to recruit 64 patients who are eligible for patellofemoral arthroplasty (PFA) and randomly assign these patients to either PFA or total knee arthroplasty (TKA).

The aims of the study are:

1. To quantify and draw inferences on observed differences in knee function for PFA and TKA at one-year post-operatively
2. To determine the complication rate of PFA versus TKA at one-year post-operatively
3. To investigate the cost effectiveness of PFA versus TKA

On 04/08/2011 the overall trial end date for this trial was extended from 31/12/2011 to 30/04/2013 to allow the team to achieve their target recruitment level.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Coventry Research Ethics Committee, 03/03/2009, ref: 09/H1210/9

Primary study design

Interventional

Study design

Single-centre randomised clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patellofemoral osteoarthritis

Interventions

All potential participants for this study will be identified by Orthopaedic Consultants in the arthroplasty clinics. Eligible patients will be randomised in a 1:1 allocation to a TKA or PFA. The patients allocated to TKA will have all of the surfaces of their knee joint replaced. The patients allocated to PFA will only have their patellofemoral articulation replaced. Both forms of treatment are well-established, but the exact details of the surgery will be left to the discretion of the surgeon in this pragmatic trial. The follow-up for both arms of the study will be equal: 12 months.

Further information can be obtained from:

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Intervention Type

Procedure/Surgery

Primary outcome(s)

Western Ontario and McMaster Osteoarthritis Index (WOMAC), used to determine knee function at 6 weeks, 3 months, 6 months and 12 months

Key secondary outcome(s)

Measured pre-operatively, 3, 6 and 12 months post-operatively:

1. UCLA Knee Rating Score
2. Oxford Knee Score
3. EuroQOL
4. Knee Society Score

Completion date

30/04/2013

Eligibility

Key inclusion criteria

1. Medically fit for an operation
2. Severe isolated patellofemoral osteoarthritis of the knee
3. Deemed suitable for a PFA by the consultant surgeon
4. Both male and female patients, aged 18 years and older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

64

Key exclusion criteria

1. Unfit for an operation
2. Tibiofemoral arthritis of the knee

Date of first enrolment

01/03/2009

Date of final enrolment

05/04/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Clinical Sciences Research Institute

Coventry

United Kingdom

CV2 2DX

Sponsor information

Organisation

University of Warwick

ROR

<https://ror.org/01a77tt86>

Organisation

University Hospitals Coventry and Warwickshire NHS Trust (UK)

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2020	28/07/2023	Yes	No
Protocol article	Protocol	23/11/2011		Yes	No