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

Submission date	Recruitment status	[ ] Prospectively registered
20/08/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/07/2023	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Juul Achten

Contact details
Warwick Orthopaedics Research Manager
Clinical Sciences Research Institute
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Single-centre randomised clinical 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
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:
Mr Matthew Costa
Clinical Sciences Research Institute
Clifford Bridge Road
Coventry CV2 2DX
United Kingdom
T: +44 (0)24 7696 8616
F: +44 (0)24 7696 8617

Intervention Type
Procedure/Surgery

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

Secondary outcome measures
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

Overall study start date
01/03/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
64 patients

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
England

United Kingdom

Study participating centre
Clinical Sciences Research Institute
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University of Warwick

Sponsor details
University House
Coventry

England
United Kingdom
CV4 8UW

Sponsor type
University/education

Website
http://www2.warwick.ac.uk/fac/med/research/csri/

ROR
https://ror.org/01a77tt86

Organisation
University Hospitals Coventry and Warwickshire NHS Trust (UK)

Sponsor details
c/o Mrs Ceri Jones
Research and Development Department
University Hospital
1st Floor Rotunda
Clifford Bridge Road
Coventry
England
United Kingdom
CV2 2DX

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research (UK)

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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