

Controlled Trial: Denervation of patella during primary knee replacement operation

Submission date 14/03/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/05/2013	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/06/2016	Condition category Musculoskeletal Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

There are two different ways of preparing the knee cap (patella) to sit and move with the new knee during total knee replacement operation. One is denervation and other is no denervation of patella. Denervation of patella is a surgical step during knee replacement operation which aims to cut away the small nerve endings around the knee cap while tidying up the worn out knee cap.

The study was conducted to enable us to determine whether denervation during knee replacement operation would improve the pain relief and functional abilities of the patients.

Who can participate?

All patients from both sexes and all age groups were eligible to participate in the study. This study recruited patients who have been wait listed for Knee replacement operation for Knee osteoarthritis without any other known cause such as trauma, rheumatoid arthritis etc (primary osteoarthritis). These patients were given all the information about the study at least 2 weeks prior to operation and those patients willing to participate in the study were consented and recruited into the study.

What does the study involve?

The study included 63 patients from each group, randomly allocated to the denervation or the no denervation group. Patients were assessed by three independent nurse practitioners who were blinded to the status of denervation at 3 months, 1 year and 2 year intervals. Patients were asked to fill up questionnaires related to some of the validated knee and functional scores. About 15 mins of patients time was involved during these assessments at each visit. The data was fully protected and anonymised. Analysis is currently being performed.

What are the possible benefits and risks of participating?

No direct benefit for research participants. Denervation of patella during knee arthroplasty has been a practice and known to surgeons for more than 10 years. Even though some surgeons express concerns about possible damage to circulation to the patella while performing the denervation procedure, there are no official reports about these adverse effects following denervation procedure. On the other hand, even though some surgeons believe that it offers better pain relief following a Knee replacement operation, the evidence is not fully proven.

Where is the study run from?
Chorley Hospital, Lancashire Teaching Hospital.

When is the study starting and how long is it expected to run for?
April 2009 and June 2010

Who is funding the study?
Lancashire Teaching Hospitals NHS Foundation Trust, Chorley Hospital (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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5 Sheriff court
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BD16 3HQ

Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Denervation of patella during primary knee arthroplasty: A randomised controlled trial

Study objectives
Null hypothesis: No difference between the denervated and not denervated group during primary knee replacement operation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tameside and Gossop Local Research Ethical committee Manchester, Approved in Jan 2009, NHS REC reference number: 08/H1013/63

Study design

Single centre randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Primary knee replacement for primary osteoarthritis

Interventions

We randomized 126 patients undergoing primary total knee replacement for primary osteoarthritis under the care of two senior authors into two groups:

Group 1 denervation group (n=63)

Group 2 no denervation group (n=63)

All patients had varus osteoarthritis and had a cruciate retaining implant. During surgery, randomization using sealed envelopes was carried out once the surgeon was satisfied that the patella did not require resurfacing. The randomization was done using computer generated numbers, which were then enclosed in sealed envelopes. All the operations were performed by two senior authors or under their direct supervision.

Patients and assessors were blinded with regards to denervation status for the duration of study.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Patellar scores
2. Oxford scores

Assessment was performed pre-operatively, 3, 12 and 24 months post operatively by three independent experienced practitioners by means of questionnaires and physical assessment. Routine demographic data including age, gender, side of surgery, duration of symptoms prior to surgery and body mass index (BMI) were recorded pre-operatively. The two groups were well matched.

Key secondary outcome(s))

1. Society Scores
2. Range of movement
3. Patient satisfaction
4. Activities of Daily Living Scores
5. Visual Analogue Scale, VAS for anterior knee pain
6. University of California and Los Angeles, UCLA activity scale

Assessment was performed pre-operatively, 3, 12 and 24 months post operatively by three independent experienced practitioners by means of questionnaires and physical assessment.

Completion date

01/05/2010

Eligibility

Key inclusion criteria

All patients, all ages, both sexes with severe painful, primary osteoarthritis of knee with varus deformity who are on the wait list for Primary Knee Replacement operations under the care of two Consultant Orthopaedic Surgeons who are supervising this research project.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients with valgus knees
2. Patients with rheumatoid or other inflammatory arthritis
3. Patients who had previous operations for trauma or infection in the same joint
4. Neurological and vascular problems.
5. Revision operations
6. Post traumatic arthritis due to previous patellar fracture or quadriceps rupture

Date of first enrolment

01/05/2009

Date of final enrolment

01/05/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

5 Sheriff court

Bingley

United Kingdom

BD16 3HQ

Sponsor information

Organisation

Lancashire Teaching Hospital NHS Trust (UK)

ROR

<https://ror.org/02j7n9748>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Lancashire Teaching Hospital NHS Trust (UK)

Results and Publications

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?
Results article	results	01/05/2014		Yes	No