

# Controlled Trial: Denervation of patella during primary knee replacement operation

<b>Submission date</b> 14/03/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/05/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/06/2016	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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?  
R S Pulavarti  
rspulavarti@yahoo.co.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Ramnadh Pulavarti

**Contact details**  
5 Sheriff court  
Bingley  
United Kingdom  
BD16 3HQ

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**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**

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 measure**

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.

### **Secondary outcome measures**

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.

### **Overall study start date**

01/05/2009

### **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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

63 in each group

### **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**

England

United Kingdom

**Study participating centre**

**5 Sheriff court**

Bingley

United Kingdom

BD16 3HQ

## **Sponsor information**

**Organisation**

Lancashire Teaching Hospital NHS Trust (UK)

**Sponsor details**

Chorley Hospital

Preston road

Chorley

Preston

England

United Kingdom

PR7 1PP

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.lancsteachinghospitals.nhs.uk/>

**ROR**

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

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Lancashire Teaching Hospital NHS Trust (UK)

## 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?
<a href="#">Results article</a>	results	01/05/2014		Yes	No