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Controlled Trial: Denervation of patella during primary knee replacement operation

Submission date
14/03/2013

Recruitment status
No longer recruiting

Registration date
20/05/2013

Overall study status
Completed

Last Edited
09/06/2016

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 osteoarthrosis 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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Contact details
5 Sheriff court
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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 osteoarthrosis

Interventions
We randomized 126 patients undergoing primary total knee replacement for primary osteoarthrosis 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 osteoarthrosis 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 movment
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 osteoarthrosis 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?
Results article	results	01/05/2014		Yes	No