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Assessing the safety of removing the inflamed joint lining tissue during knee replacement surgery

Submission date
28/09/2016

Recruitment status
No longer recruiting

Registration date
06/10/2016

Overall study status
Completed

Last Edited
29/08/2018

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Osteoarthritis is a common cause of knee pain and swelling that usually occurs in middle to old age. The damage to the knee joint may be due to knee overuse or due to a knee injury. Eventually, where there is severe knee pain knee replacement surgery may be required. In knee replacement surgery (arthroplasty), the diseased knee is replaced with an artificial joint. 85,000 knee replacements are carried out in England and Wales each year, and the number is rising. Most people who have a total knee replacement are over 65, and just over half of all patients are women. A knee replacement is usually a successful operation, however up to 10-20% of patients are unhappy with the results, even when technically it appears to have been a success. It is not always known why this is the case. One possible reason for stiffness and pain is that the lining of the knee joint, called the synovium, continues to be inflamed. Surgeons do not routinely remove the synovium, but if it is inflamed is may continue to cause symptoms for the patient, even when the joint has been replaced. This synovium can be removed at the time of surgery, but a study is needed to check that this is safe to do as there have been concerns about bleeding when it is removed. The aim of this study is to find out whether the synovium can be removed safely during knee replacement surgery. If the results from this study show that it is safe, larger studies will be carried out to find out how helpful this may be to the large number of patients who have an obviously inflamed synovium at the time of surgery.

Who can participate?
Patients aged 18 or older with knee osteoarthrtitis requiring arthroplasty

What does the study involve?
During the knee replacement operation, the surgeon looks at the joint lining tissue and decides whether it appears inflamed or not. This is done based on the colour of the joint lining - red is inflamed and yellow is not inflamed. If it is yellow and therefore not inflamed, the patient is removed from the study. For participants with an inflamed joint lining a decision is made at random to remove the joint lining or not . If the joint lining is to be removed then this is done carefully using an agreed surgical technique to avoid bleeding. The knee replacement is then done in a routine way. If the joint lining tissue is not to be removed then the surgeon goes

straight on to do the knee replacement. Following the knee replacement, participants all have the same rehabilitation. This involves physiotherapy on the ward until they are ready to go home. The research team takes note of the blood test results from before the operation and also the routine test that is done on the first day following the operation. The team also take a note of any blood transfusions required. This is to check if the participants who have the joint lining removed lose more blood. All participants are then be seen at 6 weeks and 1 year after the operation to check how well the knee moves and also to do some questionnaires to find out how happy they are with the knee replacement.

What are the possible benefits and risks of participating?
The possible benefit from participating in this study is that if a patient has an inflamed synovium that is removed, then they may have a knee replacement that works better with less likelihood of problems such as continued pain. The main risk of participating if that if the joint lining tissue is removed then there may be more bleeding and therefore a blood transfusion may be required and there may be wound healing problems.

Where is the study run from?
Freeman Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2012 to October 2015

Who is funding the study?
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Who is the main contact?
Mr Kenneth Rankin
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
Synovectomytrial

Study information

Scientific Title
A single-centre randomised controlled surgical trial to compare the safety of synovectomy versus no synovectomy during total knee arthroplasty for osteoarthritis in patients with macroscopically inflamed synovium

Study objectives
In many patients with osteoarthritic of the knee, residual inflammation of the synovium after knee replacement contributes to poor outcomes. Removal of this synovium during knee replacement surgery can be performed safely.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service: Sunderland Research Ethics Committee, 22/02/2011, ref: 10 /H0904/76

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
The trial consists of two arms and randomisation is performed intra-operatively by a research nurse attending the operating room using the ‘sealed envelope.com’ website to provide the allocation. After eversion of the patella, the synovium is evaluated by the surgeon. Criterion for confirming a macroscopically inflamed synovium is based on the colour of the intimal layer: red indicating inflammation. Patients who do not have a macroscopically inflamed synovium undergo a routine knee replacement procedure and are withdrawn from the study. Participants with confirmed macroscopically inflamed synovium are randomised to receive synovectomy or no synovectomy followed by routine implantation of the knee replacement. For the primary outcome measure (decrease in haemoglobin) the pre-operative haemoglobin is compared to the day one post-operative haemoglobin. Follow-up is performed by our research team with participants blinded until their one year follow-up. The follow-up time points are six weeks and one year post-operatively. Any transfusion requirement is documented at the six week point along with adverse events. The secondary outcome measures are knee range of movement, WOMAC, SF-36, EQ-5D and a patient satisfaction from surgery score which are measured pre-operatively and post-operatively at six weeks and one year.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Mean haemoglobin decrease from pre-operatively to day one post-operatively

Key secondary outcome(s))
1. Range of movement, measured by a research physiotherapist using a goniometer
2. Osteoarthritis symptoms, measured using the Western Ontario and McMaster Universities Arthritis Index (WOMAC)
3. Quality of life, measured using the Short Form Health Survey (SF-36)
4. Health status, measured using the EuroQol five dimensions questionnaire (EQ-5D)
5. Patient satisfaction from surgery score
All measured pre-operatively, 6 weeks post-operatively and 1 year post-operatively.

Completion date
07/10/2015

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. Female and male
3. End stage osteoarthrtitis of the knee requiring arthroplasty

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Refusal or inability to provide informed consent
2. Bilateral synchronous procedures
3. Osteoarthritis secondary to auto-immune arthropathy
4. Inability to answer questionnaires due to cognitive impairment
5. Neuromuscular disorders that would perturb rehabilitation
6. BMI more than 40

Date of first enrolment
01/11/2013

Date of final enrolment
07/10/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Freeman Hospital
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Newcastle upon Tyne Hospitals NHS Foundation Trust

Alternative Name(s)
Newcastle upon Tyne Hospitals NHS Trust

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are available from Kenneth Rankin. (kenneth.rankin2@nuth.nhs.uk) on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/08/2018		Yes	No
Basic results		06/10/2016	06/10/2016	No	No
Participant information sheet		06/10/2016	06/10/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes