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Comparison of rehabilitation outcomes after total knee arthroplasty with and without tourniquet use

Submission date	Recruitment status	[X] Prospectively registered
21/06/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/07/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/10/2018	Surgery	

Plain English summary of protocol

Background and study aim
Knee replacement surgery (arthroplasty) involves replacing a damaged, worn or diseased knee with an artificial joint. About 12,000 total knee arthroplasties (TKA) are performed every year in Sweden. About 85% of these are carried out with a tourniquet. A tourniquet is a mechanical device used during surgery to restrict blood flow, thus creating a 'bloodless' field of vision for the surgeon. The benefits are that visibility is better for the surgeon and the patient loses less blood. In order to achieve a bloodless field a blood pressure cuff is used on the thigh. The applied pressure on the skin, muscles, nerves and blood vessels can cause neuromuscular damage that contributes to weakness of the quadriceps muscle after the surgery. There are few studies that describe the effect of tourniquet use on rehabilitation after TKA and no trials have been carried out under Swedish conditions. We are therefore going to study the effect of performing TKA with and without tourniquet with respect to rehabilitation outcomes. The purpose of this study is to see if rehabilitation is accelerated and enhanced when TKA is carried out in a non-bloodless field.

Who can participate?
Patients undergoing TKA because of arthrosis, age 50 to 80.

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will be operated on with a tourniquet around the thigh, while the other group will be operated on without the use of a tourniquet. The patients will be tested by a physiotherapist before surgery, and at 3 days, 3 months and 2 years after surgery. The active range of motion in the knee will be assessed. We will time how long it takes for the patient to get up from a chair, walk three meters, turn and sit down again. The patients will be asked how painful is your leg? according to a 0-10 scale. Swelling is assessed by measuring the circumference of thigh, knee and below the knee. Quadriceps muscle function is tested by the patient being asked to perform a straight leg raise while lying on their back. After 2 years gait speed is assessed using a timed walking test and the patients are asked to fill in a questionnaire.

What are the possible benefits and risks of participating?
The participants will be more thoroughly tested by the physiotherapist. Undergoing surgery is always a risk.

Where is the study run from?
The study is run from Nyköping Hospital, Nyköping, Sörmland County Council.

When is study starting and how long is it expected to run for?
The study will run from September 2012 to March 2017.

Who is funding the study?
Centre for Clinical Research Sörmland, Uppsala University (Sweden).

Who is the main contact?
Mrs Maria Alexandersson

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Comparison of rehabilitation outcomes after total knee arthroplasty with and without tourniquet use: a randomised controlled trial

Study objectives
That knee flexion is better on day 3 in the non-tourniquet group.

Added 12/11/2014: Follow-up also at 3 months and 2 years.

On 12/11/2014 the anticipated end date was changed from 31/12/2013 to 01/03/2017.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Regional ethical review board at the Karolinska Institut in Stockholm, 09/11/2011, EPN dnr 2011 /1625-31/1

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Total knee arthroplasty

Interventions
Only senior orthopaedic surgeons who have previous experience from both operative procedures participate in the trial with a minimum of three operations from each procedure.

Each surgeon operates half of their patients with tourniquet and half without. Spinal anaesthesia is used preferentially, with general anaesthesia used only in exceptional cases. The patient lies supine on a standard operating table and is clothed in disposable garments. An anaesthesia arch is used.

One group is operated with a tourniquet around the thigh, the tourniquet being used to apply a pressure of 300mmHg and the other group is operated without the use of a tourniquet. A sagittal incision is made running straight up from anterior till the tibial tuberosity to a point about 10cm above the patella. The type of prosthesis used is the cemented NexGen (Zimmer), usually without patellar resurfacing. Infiltration with 150ml ropivacain supplemented ketorolac and adrenaline is applied during surgury. Indwelling catheter and drainage is not normally used. Staples and bandaging with Tegaderm braces, sterile elastic bandages, sterile cotton wool and compression bandages are used. If a tourniquet is used it is released after the bandaging has been applied.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Active Range of Motion (AROM) in the knee is measured before surgery, at day 3 and at 3-month control with a goniometer, with the patient lying supine.
Added 12/11/2014: Follow-up also at 2 years.

Key secondary outcome(s))
1. Timed up and go (TUG) is carried out before surgery, at day 3 and at 3-month control. TUG is a functional test in which the time taken for the patient to get up from a chair, walk three meters,

turn and sit down again is measured.
2. Visual Analaogue Scale (VAS) is used for pain assessment. The patient answers the question How painful is your leg? according to a 0-10 scale. This is done before surgery, 24 hours after surgery, 72 hours after surgery (+- 2 hrs) and at a 3-month control. The question is asked prior to training, while the patient is at rest and any additional analgesia given is noted.
3. Swelling is assessed by measuring the circumference 10cm proximal to the superior border of the patella, at the superior border of the patella and 10 cm distal to the superior border of the patella with the patient lying supine. This is done prior to surgery, at day 3 and at a 3-month control.
4. Quadriceps function is tested by the patient being asked to perform a straight leg raise while lying supine with the other leg in flexion with the foot on the base of support. The result is noted as able to/ not able to perform the action. This is carried out prior to surgery, at day 3 and at the 3-month control.

Added 12/11/2014: at 2 years the outcomes above will be assessed along with the following additional outcomes:
5. Gait speed is assessed using the 10-meter walk test. Patients are asked to walk as quickly and safely as possible for 14 meters, of which the middle 10 meters are timed.
6. The patients are asked to fill in the Oxford-12 Item Knee Score which is a well-validated outcome questionnaire, designed for use with knee arthroplasty patients.

Completion date
01/03/2017

Eligibility

Key inclusion criteria
1. Age 50 to 80
2. Cause of surgery arthrosis
3. Total knee replacement (NexGen)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Reoperative surgery.
2. Valgus deformity (> 30°)
3. Those having one-stage bilateral procedures
4. Rheumatoid arthritis
5. Secondary arthrosis
6. Body mass index (BMI) > 35

Added 12/11/2014:
7. Medical grounds discovered by the surgeon after randomization

Date of first enrolment
01/09/2012

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Nyköpings lasarett
Nyköping
Sweden
SE-61185

Sponsor information

Organisation
Uppsala University (Sweden)

ROR
https://ror.org/048a87296

Funder(s)

Funder type
University/education

Funder Name
Centre for Clinical Research Sörmland, Uppsala University (Sweden)

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	01/04/2019		Yes	No