

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

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<b>Registration date</b> 12/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/10/2018	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## 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

Mrs Maria Alexandersson

### Contact details

Nyköpings lasarett

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

### **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**

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 surgery. 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 measure**

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.

## **Secondary outcome measures**

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 Analogue 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.

## **Overall study start date**

01/09/2012

## **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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Consecutive inclusion until 80 patients are included in the study

**Key exclusion criteria**

1. Reoperative surgery.
2. Valgus deformity ( $> 30^\circ$ )
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)

### Sponsor details

Centre for Clinical Research Sörmland  
Kungsgatan 41  
Eskilstuna  
Sweden  
SE-63188

### Sponsor type

University/education

### Website

<http://www.uu.se/en/>

### ROR

<https://ror.org/048a87296>

## Funder(s)

### Funder type

University/education

### Funder Name

Centre for Clinical Research Sörmland, Uppsala University (Sweden)

## 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	01/04/2019		Yes	No