

# How to recover from total knee arthroplasty with less pain

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| <b>Submission date</b><br>24/08/2015   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>25/08/2015 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>25/08/2015       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |
|  |   | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Osteoarthritis (OA) is the most common type of arthritis, affecting millions of people worldwide. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, which can cause stiffness, pain, and a reduction in the range of movement. The knee is the most common joint to be affected by OA, and in severe cases, surgery may be the only treatment that can provide patients with relief. A total knee arthroplasty (TKA), also known as a total knee replacement, is recommended if the pain from OA is so severe that it is causing disability. In this operation, the diseased cartilage and bone is removed from the surface of the knee joint and replaced with a man-made surface of metal or plastic. Several studies have found that pain following a TKA is highest between 24 and 48 hours after surgery, and it often leads to considerable knee swelling and blood loss. The aim of this study is to see whether using a cold solution containing adrenaline in a drip during and after surgery will be better at reducing these problems than when a room temperature solution without adrenaline is used.

### Who can participate?

Senior patients undergoing a knee replacement due to degenerative knee joint osteoarthritis.

### What does the study involve?

Participants are randomly split into two groups. The first group (control group) is given a saline (salt water) irrigation (bathing of the joint) at room temperature throughout their surgery. After surgery, another 50ml of saline at room temperature is injected into the knee joint space through a drainage tube, which is left in place for four hours. The second group (treatment group) is given an irrigation containing a solution of saline and adrenaline at a cold temperature (4°C). After the operation, a further 50ml of the cold adrenaline solution is injected into the knee joint space through a drainage tube, which is in place for four hours. Patients in both groups are then given questionnaires to fill in to find out their level of pain and how well they are sleeping after the surgery. Level of swelling is measured before the operation, 48 hours, and 96 hours after the operation. The amount of fluid from the drainage tube is measured after 24 hours so that the amount of blood loss can be calculated.

What are the possible benefits and risks of participating?

There are no major benefits other than the patients in the experimental group could experience less pain and lower blood loss. There are no significant risks of participating in the study.

Where is the study run from?

Chinese PLA General Hospital (China)

When is the study starting and how long is it expected to run for?

December 2014 to June 2015

Who is funding the study?

301 Military Hospital

Who is the main contact?

Dr Long Gong

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## Contact information

**Type(s)**

Public

**Contact name**

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## Additional identifiers

**Protocol serial number**

273810

## Study information

**Scientific Title**

Effects of cold irrigation on early results after total knee arthroplasty (TKA) – A randomized, double-blind, controlled study

**Study objectives**

Patients with such an intervention experienced postoperative pain with less swelling and blood loss and thus achieve improved quality of life during early hospital stay.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Institutional Review Board of 301 (Beijing), 08/01/2014, ref: 2014-675.

### **Primary study design**

Interventional

### **Study design**

Single-centre double-blinded randomised controlled trial.

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Degenerative knee joint osteoarthritis

### **Interventions**

Control Group: Patients are intraoperatively administered with continuous irrigation of 4000ml saline of normal temperature during the whole total knee arthroplasty (TKA) procedure. Normal irrigation saline is stored in operation room at 21-24. After closure of the joint capsule, patients are irrigated with 50ml saline at normal temperature. Drainage tube was unclamped 4 hours later.

Treatment Group: Patients in treatment group were intraoperatively administered with continuous irrigation of 4000ml cold solution with 0.5% epinephrine. Irrigation solution is kept 4 in the refrigerator, which is closed to operation theater so that these cold irrigation solutions could be transported by circulating nurse in time. Epinephrine was added into cold solution following preparation of bone bed. After closure of the joint capsule, 50mL of 0.5% epinephrine cold irrigation solution is injected into the knee joint cavity by a drainage tube at the end of operation. Drainage tube was unclamped 4 hours later

Patients in both groups were provided with 48 hours patient-controlled analgesic (PCA) pump. For relieving postoperative pain, all patients received routinely Diclofenac sodium (50 mg, tid) and Parecoxib (40 mg, qd). After discharge from hospital, tramadol was used on patients' demand. Thromboprophylaxis protocol was 10mg rivaroxaban every day.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Primary outcome(s)**

Pain at rest is measured by a 100 mm visual analogue scale (VAS), at 24, 48 and 72 hours after surgery.

### **Key secondary outcome(s)**

1. Analgesic consumption is measured during hospitalisation. This depended on total doses of morphine used by PCA treatment, weak opioid analgesic and NSAID in every 12 hours
2. Drainage output was recorded and compared following extracting the drainage tube after 24 hours. Drainage output reflected dominant blood loss partly. Finally analyzed drainage output in this study resulted from deducting 50ml irrigation solution infused before surgery from recorded total output
3. Hemoglobin levels are measured 72 hours after surgery to find if levels have decreased
4. Knee joint girth as a reflection of swelling level and local inflammation was measured above 1 cm proximal to the upper border of the patella before operation, and at 48 and 96 hours after operation

### **Completion date**

01/06/2015

## **Eligibility**

### **Key inclusion criteria**

Patients undergoing primary, unilateral total knee arthroplasty (TKA) due to degenerative knee joint osteoarthritis.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Senior

### **Sex**

All

### **Key exclusion criteria**

1. Severe hypertension and cardiovascular diseases
2. Allergy to epinephrine and cold stimulation

### **Date of first enrolment**

21/12/2014

### **Date of final enrolment**

21/03/2015

## **Locations**

### **Countries of recruitment**

China

**Study participating centre**  
**Chinese PLA General Hospital**  
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100853

## Sponsor information

**Organisation**  
301 Military Hospital

**ROR**  
<https://ror.org/04gw3ra78>

## Funder(s)

**Funder type**  
Hospital/treatment centre

**Funder Name**  
301 Military Hospital

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Data sharing statement to be made available at a later date