# A randomized controlled trial on effects of Cryo /Cuff in early rehabilitation of total knee arthroplasty

Submission date	Recruitment status	Prospectively registered
05/04/2017	No longer recruiting	[] Protocol
Registration date	Overall study status	Statistical analysis plan
10/04/2017	Completed	Results
Last Edited	Condition category	Individual participant data
10/04/2017	Musculoskeletal Diseases	[] Record updated in last year

# Plain English summary of protocol

#### Background and study aims

Osteoarthritis (OA) is the most common type of arthritis, which most often affects the knee. 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 a person's range of movement. A knee joint replacement is a common procedure where the weight bearing surfaces of the knee joint are replaced with metal and plastic components to relieve the pain and disability brought on by OA. Cryotherapy (cold therapy) is widely used for treating sports injury and for providing pain relief after surgery, as it helps to reduce inflammation (swelling). It is not known however, how deep this treatment can reach into the knee joint. The Cryo/Cuff is a device of combination of cryotherapy and compression. With help of compression, Cryo/Cuff can extend the depth that cryotherapy can reach. The aim of this study is to find out whether Cryo /Cuff is an effective and safe treatment for the management of pain, swelling, blood loss, post-operative hospital stay and range of motion of knee in patients who have had knee replacement surgery.

#### Who can participate?

Adults who have OA and need a total knee replacement.

#### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive usual treatment, which does not involve cooling. Those in the second group use the Cryo/Cuff device for three hours immediately after surgery and then for an hour twice a day for the next three days. Before surgery and for five days after, participants are asked to rate their pain levels using a numbered scale. In addition, the length of their hospital stay, swelling and bleeding, and range of motion of the affected knee are assessed in the days following surgery.

What are the possible benefits and risks of participating? Participants who are allocated to receive treatment with Cryo/Cuff may benefit from a reduction in pain, swelling and blood loss after surgery, shortening their hospital stay. There is a small risk of discomfort, frostbite or deep vein thrombosis (a blood clot in a major vein in the leg) when using the Cryo/Cuff.

Where is the study run from? Peking Union Medical College Hospital (China)

When is the study starting and how long is it expected to run for? June 2016 to January 2017

Who is funding the study? Peking Union Medical College Hospital (China)

Who is the main contact? Mrs Bingdu Tong

# **Contact information**

**Type(s)** Scientific

**Contact name** Mrs Bingdu Tong

# **Contact details**

Department of Orthopedics Peking Union Medical College Hospital Chinese Academy of Medical Sciences Shuai fu Yuan No. 1 Dongcheng District Beijing China 100730

# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers N/A

# Study information

Scientific Title

A randomized controlled trial to evaluate whether Cryo/Cuff compared to placebo can better management of pain, swelling, blood loss, range of motion in postoperative total knee arthroplasty patients

#### **Study objectives**

The aim of this study is to investigate whether Cryo/Cuff is safe and effective for management of pain, swelling, blood loss, postoperative hospital stay and ROM of knee in postoperative TKA patients and to establish a better Cryo/Cuff protocol to promote early rehabilitation.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The Ethical Committee at Peking Union Medical College Hospital, 21/06/2016, ref: ZS-1096

#### Study design

Single-centre randomised controlled trial.

**Primary study design** Interventional

Secondary study design

Study setting(s) Hospital

**Study type(s)** Treatment

#### Participant information sheet

No participant information sheet available

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

Degenerative knee joint osteoarthritis

#### Interventions

Patients are randomised into either the Cryo/Cuff group or control group using computergenerated randomization sequence (SAS Statistical Software 9.1.3).

Intervention group: Participants receive 3 hours' Cryo/Cuff immediately after surgery and one hour twice daily for consecutive three days.

Control group: Participants receive care as usual, which does not involve application of as cooling device.

All the patients share the same analgesic strategy and rehabilitation protocol. All patients receive the same oral and written information with emphasis on postoperative pain as a natural consequence of surgery as well as the patient's own responsibility for ROM exercises.

Follow up involves assessing range of motion and takes place 1 and 2 weeks after the operation.

### Intervention Type

#### Primary outcome measure

Pain is measured using the visual analogue scale (VAS) at rest and during exercise at baseline (1 day before surgery) and 1-5 days after surgery.

### Secondary outcome measures

1. Opioid consumption is measured by anesthesiologist at 72 hours removal of the sufentanil PCA pump

2. Swelling is measured using knee girth in millimeters at mid-patella with the knee in maximal extension at baseline (1 day before surgery) and 2 to 5 days after surgery

3. Wound drainage is assessed by the independent member of the research team at 48 hours

4. Hemoglobin is measured using blood test at admission, 1, 3 and 5 days after surgery

5. Blood transfusion rate is measured by the independent member of the research team at discharge

6. Range of motion is measured according to standard reference points (the greater throchanter, the lateral condyle of femur, and the later malleolus) with a goniometer in intervals of 1° and recorded as maximum active extension and flexion at baseline (one day before surgery), 1 and 2 weeks after surgery

7. Length of post-operative hospital stay is assessed by the independent member of the research team at patients' discharge

# Overall study start date

21/06/2016

# **Completion date**

23/01/2017

# Eligibility

# Key inclusion criteria

1. Aged 18 to 80 years

2. Degenerative osteoarthritis need for total knee arthroplasty

3. Initial unilateral total knee arthroplasty patients

4. Agreeing to participate in the study

# Participant type(s)

Patient

**Age group** Adult

**Lower age limit** 18 Years

**Sex** Both

**Target number of participants** 98

#### Key exclusion criteria

1. Patients had abnormal blood coagulation

2. Patients who cannot tolerate Cryo/Cuff

3. Patients were diagnosed as rheumatoid arthritis, traumatic osteoarthritis, ankylosing spondylitis, hemophilic arthritis, peripheral vascular disease

4. Cold urticaria

5. Preoperative anticoagulation, patients had preoperative deep vein thrombosis (DVT)

6. Preoperative history of anemia

### Date of first enrolment

01/07/2016

Date of final enrolment 31/12/2016

# Locations

**Countries of recruitment** China

**Study participating centre Peking Union Medical College Hospital** Chinese Academy of Medical Sciences Shuai fu Yuan No. 1 Dongcheng District Bejing China 100730

# Sponsor information

### Organisation

Peking Union Medical College Hospital

### **Sponsor details**

Chinese Academy of Medical Sciences Shuai fu Yuan No. 1 Dongcheng District Beijing China 100730

**Sponsor type** Hospital/treatment centre ROR https://ror.org/04jztag35

# Funder(s)

Funder type Hospital/treatment centre

**Funder Name** Peking Union Medical College Hospital

Alternative Name(s) PUMCH

**Funding Body Type** Government organisation

Funding Body Subtype Local government

**Location** China

# **Results and Publications**

**Publication and dissemination plan** Planned publication in a high-impact peer reviewed journal

Intention to publish date 23/01/2018

Individual participant data (IPD) sharing plan

**IPD sharing plan summary** Not expected to be made available