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

Submission date
05/04/2017

Recruitment status
No longer recruiting

Registration date
10/04/2017

Overall study status
Completed

Last Edited
10/04/2017

Condition category
Musculoskeletal Diseases

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

Protocol serial number
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

Study type(s)
Treatment

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 computer-generated 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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes