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How to recover from total knee arthroplasty with less pain

Submission date
24/08/2015

Recruitment status
No longer recruiting

Registration date
25/08/2015

Overall study status
Completed

Last Edited
25/08/2015

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, 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?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Single-centre double-blinded randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 applicated with 50ml saline at normal temperature. Drainage tube was unclamped 4 hours later.

Treatment Group: Patients in treatment group were intraoperatively administrated with continuous irrigation of 4000ml 4 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 measure
Pain at rest is measured by a 100 mm visual analogue scale (VAS), at 24, 48 and 72 hours after surgery.

Secondary outcome measures
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

Overall study start date
11/12/2014

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

Age group
Senior

Sex
Both

Target number of participants

Sample size estimation was based on detecting the difference in VAS pain scores. The estimated number of more than 150 patients in each group was enough to detect a 20% difference between groups with alpha set at 0.05 and beta 0.1. An additional 10% of total participants were planned in each group to make up for possible loss.

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
Department of Orthopedics
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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04gw3ra78

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
301 Military Hospital

Results and Publications

Publication and dissemination plan
To submit to Journal of aArthroplasty

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

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