ISRCTN34325028 https://doi.org/10.1186/ISRCTN34325028

Effects of modified drainage on total knee arthroplasty

Submission date
16/09/2018

Recruitment status
No longer recruiting

Registration date
01/10/2018

Overall study status
Completed

Last Edited
01/10/2018

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. It 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 (total knee arthroplasty, TKA) 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.
Drainage is a traditional method to reduce blood loss, pain and complications. It is not known however, what is the best method of drainage for the patients with TKA. The aim of this study is to find out whether a modified drainage 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 three groups.
Group A: traditional drainage, negative pressure drainage 4 hours after the operation of total knee replacement.
Group B: modified drainage, normal pressure drainage for 12 hours, negative pressure drainage for 12 hours.
Group C: No drainage.
The blood loss, VAS pain scores, 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 modified drainage may benefit from a reduction in blood loss, 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 modified drainage.

Where is the study run from?
The Second Affiliated Hospital, Zhejiang University School of Medicine (China)

When is the study starting and how long is it expected to run for?
Jan 2017 to June 2018

Who is funding the study?
The Second Affiliated Hospital, Zhejiang University School of Medicine (China)

Who is the main contact?
Dr Wei Wang

Study website
N/A

Contact information

Type(s)
Scientific

Contact name
Dr Wei Wang

Contact details
No.88 Jiefang Rd
Hangzhou
China
310000

Additional identifiers

EudraCT/CTIS number
NA

IRAS number

ClinicalTrials.gov number
NA

Secondary identifying numbers
NA

Study information

Scientific Title
A randomized controlled trial on effects of a modified drainage on total knee arthroplasty

Study objectives
A modified drainage reduces the blood loss in total knee replacement compared with traditional drainage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Second Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China, 10/02/2017, 2017-167

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
No participant information sheet available

Health condition(s) or problem(s) studied
Total knee replacement for osteoarthritis

Interventions
Participants are randomly allocated to one of three groups. Three groups all underwent general anaesthesia. The same surgeon performed the procedure. Mean arterial pressure of 60 to 70 mmHg and femoral nerve block with a catheter was maintained for postoperative pain management. The tourniquet was inflated to 100 to 120 mmHg. All drainage bottles were Drainobag® 600 (B. Braun Medical Inc., Melsungen, Germany).
Group A: traditional drainage, negative pressure drainage 4 hours after the operation of total knee replacement.
Group B: modified drainage, normal (atmospheric) pressure drainage for 12 hours, negative pressure drainage achieved by by pumping 500 ml air out of the drainage bottle for 12 hours.
Group C: No drainage.
Knee range of movement (ROM), including isometric quadriceps and straight leg raise exercises, were encouraged if the pain was tolerable. Passive movement with a continuous passive motion machine was encouraged on the second postoperative day.The follow up was 90 days post-operation.

Intervention Type
Procedure/Surgery

Primary outcome measure
Blood loss determined using haemoglobin levels before surgery and 1, 2 and 3 days after surgery.

Blood volume (BV) was estimated according to the method of Nadler et al. taking sex, body mass index, and height into account. For males BV = (0.3669 x height3) + (0.03219 x weight) + 0.6041 and for females BV = (0.3561 x height3)+ (0.03308 x weight) + 0.1833.
Total blood loss is calculated from total hemoglobin loss (Hbloss), which in turn is calculated from the difference between preoperative Hb and the minimum Hb during the hospital stay (postoperative day 2 in our case): Blood loss (in mL) = 100 mL/dL x Hbloss/Hbi
Hbloss = BV x (Hbi – Hbe) x 10 dL/L + Hbt
Hbi = Hb concentration before surgery (g/dL)
Hbe = Hb concentration during hospital stay (g/dL)
Hbt = Total amount of allogeneic Hb transfused (g).
Because there were no transfusions, this variable was dropped from the equation in our study.

Secondary outcome measures
1. Pain at rest measured on a visual analogue scale (VAS) on the day after surgery and documented by the nurse on duty
2. Complications. Wound status was documented daily. Oozing from the wound persisting beyond 2 days after surgery, bullae formation, subcutaneous hematoma that needed aspiration or surgical drainage, and wound infections that required additional treatmentssuch as antibiotic coverage or surgical debridement were recorded.

Overall study start date
01/01/2017

Completion date
01/06/2018

Eligibility

Key inclusion criteria
Adults who have OA and need a total knee replacement.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Abnormal blood coagulation
2. Diagnosed with rheumatoid arthritis, traumatic osteoarthritis, ankylosing spondylitis, hemophilic arthritis or peripheral vascular disease
3. Cold urticaria

4. Preoperative anticoagulation, for example in patients with preoperative deep vein thrombosis (DVT)
5. Preoperative history of anemia

Date of first enrolment
01/03/2017

Date of final enrolment
01/03/2018

Locations

Countries of recruitment
China

Study participating centre
The Second Affiliated Hospital, Zhejiang University School of Medicine
No.88 Rd Jiefang, Hangzhou, Zhejiang Province
Hangzhou
China
310000

Sponsor information

Organisation
The Second Affiliated Hospital, Zhejiang University School of Medicine

Sponsor details
No.88 Jiefang Rd
Hangzhou
China
310000
860571-13656671144
sunny01@zju.edu.cn

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/059cjpv64

Funder(s)

Funder type
Not defined

Funder Name
Natural Science Foundation of Zhejiang Province (LQ18H060001)

Funder Name
Zhejiang Province Medical and Health project (2018269731)

Funder Name
Chinese Medicine Research Program of Zhejiang Province (2015ZB028)

Funder Name
National Natural Science Foundation of China (81602312)

Results and Publications

Publication and dissemination plan
We will report the study results 1 year after the trial has ended.

Intention to publish date
01/01/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Available on request