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Blood loss and knee function after unicompartmental knee replacement or total knee replacement surgery

Submission date	Recruitment status	[ ] Prospectively registered
06/04/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/04/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/04/2020	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Knee replacement, also known as knee arthroplasty, is a surgical procedure to replace the weight-bearing surfaces of the knee joint to relieve pain and disability. It is most commonly performed for osteoarthritis, and also for other knee diseases such as rheumatoid arthritis and psoriatic arthritis.
Unicompartmental knee arthroplasty (UKA) is a surgical procedure used to relieve arthritis in one of the knee compartments in which the damaged parts of the knee are replaced. UKA surgery may reduce post-operative pain and have a shorter recovery period than a total knee arthroplasty (TKA) procedure.
Utilization of tourniquet is considered to compromise the outcome of knee arthroplasty. This study aims to evaluate the hidden blood loss and function restoration of UKA without tourniquet by comparing with total knee arthroplasty (TKA).

Who can participate?
Adults over 18 years, scheduled to undergo UKA or TKA

What does the study involve?
This study is a retrospective analysis of patient records looking at patients who underwent UKA or TKA without tourniquet.

What are the possible benefits and risks of participating?
None.

Where is the study run from?
Department of Orthopedic Surgery, The First People's Hospital of Huzhou, Huzhou (China)

When is the study starting and how long is it expected to run for?
August 2017 to December 2019

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019035

Study information

Scientific Title
Blood loss and knee function after unicompartmental knee arthroplasty (UKA) without tourniquet

Acronym

BLAKFAUKAWT

Study objectives
1. UKA or TKA without tourniquet results in lower blood loss compared to with tourniquet.
2. UKA without tourniquet results in less HBL compared with TKA
3. UKA without tourniquet enjoys a better outcome than TKA

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/06/2019, Medical Ethics Committee of The First People's Hospital of Huzhou (The First People's Hospital of Huzhou, 158 Guangchang Back Rd, Wuxing District, Huzhou, 313000, China; +86 (0)572 2508930; hzyyllwyh@163.com), ref: 2019035

Study design
Single-center retrospective controlled study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
In this retrospective study, patients were included from August 2017 to October 2018. Both the UKA group and the TKA group underwent procedure without the utilization of tourniquet during the whole process.
The gender, age, body mass index, American Society of Anesthesiologists score, Kellgren-Lawrence grade, perioperative Hb, and volume of hidden blood loss (HBL) were recorded and analysed.
Knee function was assessed at 3 months and 12 months after the procedure by using HSS score.

Intervention Type
Procedure/Surgery

Primary outcome measure

1. Mean volume of HBL during the procedure (ml)
2. Knee function assessed at 3 months and 12 months after the procedure by HSS score

Secondary outcome measures
Hb level measured using blood test on the 2nd day, 4th day, 6th day, 8th day postoperatively

Overall study start date
01/06/2017

Completion date
30/12/2019

Eligibility

Key inclusion criteria
1. Primary UKA or TKA
2. Kellgren-Lawrence (KL) grade of medial knee osteoarthritis grade

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
56 cases of UKA, and 56 cases of TKA

Total final enrolment
112

Key exclusion criteria
1. Preoperative abnormality in coagulation function, hematonosis history
2. Postoperative poor general situation
3. More than 2000ml per day in fluid infusion
4. Simultaneous bilateral UKA or TKA, and UKA or TKA secondary to a failed arthroplasty procedure

Date of first enrolment
01/08/2017

Date of final enrolment
30/10/2018

Locations

Countries of recruitment
China

Study participating centre
Department of Orthopedic Surgery
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Sponsor information

Organisation
The First People's Hospital of Huzhou

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Zhejiang University School of Medicine, Second affiliated hospital

Results and Publications

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

Intention to publish date

04/08/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request