Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Efficacy of Bone Wax Application following Femoral Neck Osteotomy in Controlling Blood Loss in Total Hip Arthroplasty via Direct Anterior Approach

Protocol summary

Study aim

To determine the efficacy and safety of bone wax in controlling blood loss during total hip arthroplasty (THA) via the direct anterior approach (DAA)

Design

A randomized clinical trial with two-arm parallel groups, which is triple-blinded and performed on 100 patients. For randomization, the permuted balanced block method and randl() function of MS Excel are used.

Settings and conduct

The patients are admitted from hip clinic of Imam-Khomeini Hospital, and undergo THA with/without bone wax based on their groups by an expert surgeon. The outcome variables will be assessed during admission and follow-up. The intervention group is specified on a folded removable label on the patient's form, which is opened only in the operation room and then discarded. None of the patients, assessor, and analyzer researchers are aware of the groups, which will be decoded after data analysis is finished.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with primary hip osteoarthritis indicated for THA, who signed informed consent formula and undergo spinal anesthesia. Exclusion criteria: Bleeding disorders, thromboembolic events, high-risk comorbidities (heart, kidney, and liver failure), inflammatory arthritis, acute hip fracture, developmental dysplasia of hip (>=2), revision arthroplasty, antithrombotic medications, impaired coagulation profile, non-spinal anesthesia, and not participating in the follow-up.

Intervention groups

Intervention group: Standard THA is performed via DAA. However, bone wax is applied on femoral cut surface following neck osteotomy and discarded when femoral broaching is to be done. Control group: Standard THA via DAA without using bone wax

Main outcome variables

The study outcomes include apparent and total blood loss, measured by the decrease in hemoglobin and hematocrit on the 3rd and 5th postoperative days, need for transfusion, and adverse events.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200305046700N1**
Registration date: **2020-04-25, 1399/02/06**
Registration timing: **prospective**

Last update: **2020-04-25, 1399/02/06**
Update count: **0**

Registration date

2020-04-25, 1399/02/06

Registrant information

Name

Mohammadreza Razzaghof

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Efficacy of Bone Wax Application following Femoral Neck Osteotomy in Controlling Blood Loss in Total Hip Arthroplasty via Direct Anterior Approach

Public title
The Effect of Bone Wax on Controlling Blood Loss during Total Hip Replacement Surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with hip degenerative joint disease (ICD-10-CM ; M16) with no age and sex limits, and not considering the severity of the disease, who are candidates for elective primary total hip arthroplasty based on the clinical and radiographic workup The patients should complete and sign the informed consent formula. The anesthesia method should be spinal anesthesia.
Exclusion criteria:
Any bleeding disorder (ICD-10-CM; D65-D69) including platelet disorders like von Willebrand disease, and coagulation disorders like hemophilia History of venous thromboembolic accidents like deep vein thrombosis (DVT), pulmonary thromboembolism (PTE), cerebrovascular accidents (CVA), and myocardial infarction (MI) High-risk medical comorbidities like chronic kidney disease (GFR< 60 mL/min), liver, and heart failure (NYHA classes III , IV) Inflammatory arthritis of hip joint (ICD-10-CM; M05-M14) like rheumatoid arthritis Total hip arthroplasty due to acute proximal femoral fracture Total hip arthroplasty due to developmental dysplasia of hip (DDH) type II and more Revision total hip arthroplasty The use of antithrombotic drugs (ATC code; B01) including vitamin K antagonists (B01AA) like warfarin, platelet aggregation inhibitors (B01AA) like clopidogrel, heparin group (B01AB), Factor X inhibitors (B01AF) like rivaroxaban, direct thrombin inhibitors (B01AE) like dabigatran Impaired coagulation laboratory profile including INR>1.1, aPTT> 1.4, PT> 13.5, or thrombocytopenia < 150,000 per microliter Any anesthesia method other than spinal anesthesia Patient cannot or do not want to continue participating in the study or follow-up for any reason
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Each included patient is assigned a unique number. Using the permuted balanced block method and randomization formula in Microsoft Office Excel 365 software, we will create the table of randomized allocation of the patients into two groups of the study (intervention or control). There will be an equal chance of being randomly assigned to each of the two groups of the study. We will assume six blocks of four (AABB, BBAA, ABAB, BABA, ABBA, BAAB). The patients will be divided into sequentially numbered groups of four. The groups will be entered into a column in MS Excel sheet. In the next column, the blocks are entered in order until the patients' groups are finished. Then, the blocks will be randomized using the Randl() formula. The block in front of each group determines the intervention group (A, B) for the members of that group, for example, for block AABB, the 1st patient will be assigned to group A, 2nd patient A, 3rd patient B, and 4th patient B. Therefore, each patient will be randomly allocated to one of the two intervention groups of the study, i.e., intervention (A) or control (B), based on his unique number.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the patient is not aware of his intervention group, hence the blinding of the patient. The group of each patient is assigned to his case report formula as a removable folded label. It will be opened in the operation room and discarded subsequently after the surgeon becomes aware of the intervention group of the patient. Therefore, the outcome assessor physician, who will collect data regarding blood loss and other clinical data, will not be aware of the intervention group of the patients, hence the blinding of the outcome assessor physician. Finally, the data analyzer will not also be aware of the intervention group of the patients. He will analyze the data based on A and B groups and after the end of data analysis, the A and B groups will be decoded. Thus, this trial will be triple-blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Imam Khomeini Hospital Complex/ Tehran University of Medical Sciences

Street address
Imam Khomeini Hospital Complex, East Baqerkhan Street, North Chamran Highway
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2020-04-15, 1399/01/27
Ethics committee reference number
IR.TUMS.IKHC.REC.1399.032

Health conditions studied

1

Description of health condition studied
Primary hip degenerative joint disease
ICD-10 code
M16.10
ICD-10 code description
Unilateral primary osteoarthritis, unspecified hip

Primary outcomes

1

Description
Apparent blood loss
Timepoint
At the end of operation
Method of measurement
Apparent blood loss is defined as the sum of blood in the suction bottle and blood absorbed in the used long gauze pads. The volume of blood absorbed within the long gauze pads is calculated by the difference between the weight of soaked and dry long gauze pads divided by blood density (1.060 gr/mL).

2

Description
Total blood loss
Timepoint
The 3rd and 5th post-operative days
Method of measurement
Nadler formula is used total blood volume of each patient: TBV [mL] = (0.0003669 × height3[cm]) + (32.19 × body weight [Kg]) + 604 (for males) TBV [mL] = (0.0003561 × height3[cm]) + (33.08 × body weight [Kg]) + 183 (for females) Mercuriali formula is used to calculate total blood loss based on pre- and post-operative (3rd and 5th days) hematocrits: Estimated Blood Loss [mL] = TBV [mL] * (Hctpreop- HctPOD5) + Transfused pRBC volume [mL] Good formula is used to calculate total blood loss based on pre- and post-operative (3rd and 5th days) hemoglobins: Hb_loss [gr]=TBV[mL]×(Hb_preop [gr/dL]-Hb_postop [gr/dL])×0.01[dL/mL]+Hb_t [gr]Total Blood Loss(mL)=(Hb_loss [gr]×100(mL/dL))/(Hb_preop [gr/dL])

3

Description
safety
Timepoint
On postoperative follow-up at least for 6 months
Method of measurement
Clinical and radiographic assessment of the patient over the postoperative follow-up

Secondary outcomes

1

Description
Need for transfusion of packed-RBCs
Timepoint
During the surgery or the admission period following surgery
Method of measurement
The volume of received packed RBCs

Intervention groups

1

Description
Intervention group: Intervention is defined as temporary application of appropriate amount -2.5 gr- of bone wax on the cut surface of femoral neck right after femoral neck osteotomy until the broaching of femur is performed. Subsequently the bone wax is discarded
Category
Treatment - Surgery

2

Description
Control group: In this group, the routine total hip arthroplasty is performed without using bone wax.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Joint Reconstruction Research Center/ Tehran University of Medical Sciences
Full name of responsible person
Seyed Mohammad Javad Mortazavi
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Joint Reconstruction Research Center, Imam Khomeini Hospital Complex, East Baqerkhan Street, North Chamran Highway
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammadreza Razzaghof

Position
Resident of Orthopedics Surgery

Latest degree
Medical doctor

Other areas of specialty/work
Orthopedics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available