Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of oral clonidine premedication with placebo on perioperative blood loss in total hip arthroplasty surgery patients

Protocol summary

Study aim

Effect of oral clonidine premedication on perioperative blood loss in elective primary total hip arthroplasty.

Design

A randomized controlled, double blinded clinical trial with parallel groups, on 34 patients. Randomization is done by the block randomization concealed in sequentially numbered, opaque, sealed envelopes.

Settings and conduct

Trial participants, investigators, healthcare providers for participants and outcome assessors are kept blind. Patients are randomly divided into two groups of 17. 90 minutes before surgery, the intervention group receives 0.2 mg clonidine tablets and the control group a placebo tablet. During operation, mean blood pressure is kept 70-80 mm Hg. The total amount of bleeding is measured by weight of blood gases, blood in suction bottle and around the operative site. Transfusion is done if the bleeding rate exceeds the allowable blood loss or if the patient develops hemodynamic instability and the amount is recorded. After surgery, hemoglobin is measured on the first and third day and transfusion rate is recorded.

Participants/Inclusion and exclusion criteria

ASA class 1 and 2 patients between 18 and 75 years scheduled for unilateral elective primary total hip arthroplasty are enrolled. Patients with ASA class 3 and 4, BMI> 30, hemoglobin<10, severe liver and kidney disease, coagulation disorder, alcoholics, taking anticoagulants, revision total hip arthroplasty or previous surgery in the operated area are excluded.

Intervention groups

Patients in the clonidine group are given 0.2 mg oral clonidine and in the control group, a placebo tablet is given.

Main outcome variables

Intraoperative blood loss, postoperative hemoglobin level, blood transfusion rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131108015322N5**
Registration date: **2021-04-07, 1400/01/18**
Registration timing: **prospective**

Last update: **2021-04-07, 1400/01/18**
Update count: **0**

Registration date

2021-04-07, 1400/01/18

Registrant information

Name

Shideh Dabir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2595

Email address

sdabir@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral clonidine premedication with placebo on perioperative blood loss in total hip arthroplasty surgery patients

Public title
Effect of oral clonidine premedication on blood loss in total hip arthroplasty
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ASA class 1 and 2 patients Elective total hip arthroplasty Primary total hip arthroplasty
Exclusion criteria:
ASA 3 and 4 patients Patients with BMI greater than 30 Patients with Hb less than 10 Patients with severe liver or kidney diseases Patients taking anticoagulants patients with coagulation disorders Alcoholic patients Revision total hip arthroplasty Patients with previous surgery in the operated area
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
To assign patients to two groups, randomization is done by the block randomization method and concealed in sequentially numbered, sealed, opaque envelopes. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Then envelopes are glued and placed inside the box, respectively. At the time of the assignment, according to the order of entry of eligible participants into the study, the relevant enveloper is opened in order and the assigned group of that participant is revealed.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Participants, investigators, healthcare providers for participants and outcome assessors are kept blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Arabi St., Yemen St., Velenjak, Shahid Beheshti University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2021-01-31, 1399/11/12
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.1080

Health conditions studied

1

Description of health condition studied
Intraoperative and postoperative blood loss in total hip arthroplasty
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The amount of bleeding during the operation
Timepoint
After intervention during surgery
Method of measurement
Weighing blood gases, amount of blood in the suction bottle, blood in the operative site

Secondary outcomes

1

Description
Postoperative hemoglobin level
Timepoint
On the first and third day after surgery
Method of measurement
Measured from a blood sample

2

Description
Blood transfusion rate
Timepoint
During surgery and in the postoperative period

Method of measurement
Number of transfused units of blood

Intervention groups

1

Description
Intervention group: Patients receiving clonidine tablet
Category
Treatment - Drugs

2

Description
Control group: Patients receiving placebo tablet
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arabi St., Yemen St., Velenjak, Taleghani Hospital
Full name of responsible person
Ṡhideh dabir
Street address
Arabi St., Yemen St., Velenjak, Taleghani Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ali Dabbagh
Street address
Fourth Floor, Anesthesiology Research Center, taleghani Hospital, Arabi St., Yemen St., Velenjak
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Web page address
https://arc.sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shideh dabir
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Shideh Dabir

Position

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Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable