

# 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 envelope 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**

Shideh dabir

**Street address**

Arabi St., Yemen St., Velenjak, Taleghani Hospital

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**Postal code**

1985717413

**Phone**

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**Email**

shdabir@yahoo.com

**Web page address**

http://taleghani.sbm.ac.ir/

**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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**Email**

alidabbagh@sbmu.ac.ir

**Web page address**

https://arc.sbm.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

**Street address**

2nd floor, Department of Anesthesiology, Taleghani Hospital, Arabi St., Yaman St. Velenjak

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Shideh Dabir

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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