# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

24 Jun 2026

## Evaluation the Effect of Ascorbic Acid compared to normal saline on the hidden blood loss in total hip arthroplasty

### Protocol summary

**Study aim**
In this study we are aiming to investigate the effect of the antioxidant agent of ascorbic acid on the amount of hidden blood loss in total hip arthroplasty.

**Design**
A double-blind randomized controlled trial with two parallel groups

**Settings and conduct**
In this randomized controlled clinical trial, 70 patients which are scheduled for THA will be consecutively assigned into two groups in a 1:1 ratio. The patients in group A will receive three doses of ascorbic acid. The patients in group B will receive only normal saline as a control group. In this double-blind study, patients and data collectors are blinded and unaware of the patient's assigned group. Informed consent will be obtained from all the patients prior to the surgery.

**Participants/Inclusion and exclusion criteria**
In this randomized controlled clinical trial, 70 patients who are scheduled for total hip arthroplasty will be included. Exclusion criteria will be the history of thromboembolic events like deep vein thrombosis or pulmonary embolism; a history of cardiovascular disease; clotting disorders including abnormal PT, PTT or INR; being in pregnancy or in the lactation period; drug abusers or alcoholics; severe renal dysfunction; severe infection; the preoperative hemoglobin < 10 g/dL, and diagnosis of inflammatory arthritis

**Intervention groups**
The patients in group A will receive the first ascorbic acid dose (1 g in 10 mL) at the beginning of the surgery. Another dose of ascorbic acid (1 g in 10 mL) will be infused during the surgery. After the surgery, an additional dose of ascorbic acid (1 g in 10 mL) will be infused during the first 12h postoperatively. The patients in group B will receive only normal saline as a control group.

**Main outcome variables**
The primary outcome measures will be total blood loss calculated by the drop in Hb level and estimated blood volume adjusted for the weight and height of the patients

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20221104056393N2**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-12, 1402/05/21**
Update count: **0**

**Registration date**
2023-08-12, 1402/05/21

**Registrant information**

**Name**
Pooya Hosseini-Monfared

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 2200 1072

**Email address**
pomonfared@sbmu.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-08-01, 1402/05/10

**Expected recruitment end date**
2023-09-01, 1402/06/10

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation the Effect of Ascorbic Acid compared to normal saline on the hidden blood loss in total hip arthroplasty

**Public title**

The Effect of Ascorbic Acid on the blood loss in Total Hip Arthroplasty

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Candidates of total hip arthroplasty due to osteoarthritis Patients who provide written informed consent to participate in this study.

**Exclusion criteria:**

history of thromboembolic events like deep vein thrombosis or pulmonary embolism history of cardiovascular disease like myocardial infarction or atrialfibrillation clotting disorders including abnormal PT, PTT or INR being in pregnancy or in the lactation period drug abusers or alcoholics severe renal dysfunction severe infection the preoperative hemoglobin of < 10 g/dL diagnosis of inflammatory arthritis like rheumatoid arthritis, pigmented villonodular synovitis and etc

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this randomized controlled clinical trial, the patients will be consecutively and in a 1:1 ratio assigned into two groups based on a simple randomization method. The surgeon is informed about the assigned group for each person by a sealed letter.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this double-blind study, patients are evaluated with random ID numbers assigned to them by the researcher. Patients and the data collector will be blind. Patients are kept unaware of their group assignment and the intervention they are receiving. Both the treatment and control groups receive identical instructions and support. The data collector is kept blind to the group assignment of each patient and will record the results only according to the patient IDs.

**Placebo**

Not 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**

Azar dead end alley, Sharifi Manesh street., Pole Roomi, Tajrish

**City**

Tehran

**Province**

Tehran

**Postal code**

1964714953

**Approval date**

2023-06-27, 1402/04/06

**Ethics committee reference number**

IR.SBMU.MSP.REC.1402.130

## Health conditions studied

### 1

**Description of health condition studied**

Total Hip Arthroplasty

**ICD-10 code**

M16.1

**ICD-10 code description**

Unilateral primary osteoarthritis of hip

## Primary outcomes

### 1

**Description**

total blood loss

**Timepoint**

Before intervention, 24h after intervention

**Method of measurement**

amount of Hemoglobin drop

## Secondary outcomes

### 1

**Description**

Transfusion rate

**Timepoint**

Before the intervention, 24h after the intervention

**Method of measurement**

number of units of blood transfused

## Intervention groups

### 1

**Description**

Intervention group: The patients in the intervention group will receive the first ascorbic acid dose (1 g in 10 mL) at the beginning of the surgery. Another dose of ascorbic acid (1 g in 10 mL) will be infused during the surgery. After the surgery, an additional dose of ascorbic acid (1 g in 10mL) will be infused postoperatively during the first 12h.

**Category**

Treatment - Surgery

### 2

**Description**

Control group: The patients in the control group will receive only normal saline.

**Category**

Treatment - Surgery

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Akhtar Hospital

**Full name of responsible person**

Seyyed Mohammad Qoreishi

**Street address**

Azar dead end alley, Sharifi Manesh St., Pole Roomi, Tajrish

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pomonfared@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**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**

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**

Seyyed Mohammad Qoreishi

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

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## Person responsible for updating data

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Medical Intern
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A Level or less
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pomonfared@sbmu.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is 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**
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**
Yes - There is 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
**Title and more details about the data/document**
Information about the main outcome can be shared after making the individuals undetectable
**When the data will become available and for how long**
Access will be granted 6 months after the results of the study are published.
**To whom data/document is available**
Researchers and medical specialist
**Under which criteria data/document could be used**
based on the Ministry of Health and Medical Education criteria for clinical trials
**From where data/document is obtainable**
Orthopedic department of Shahid Beheshti Medical University
**What processes are involved for a request to access data/document**
The data will be provided after reviewing the researcher's request and providing sufficient documentation of their research and the reason for using the data.
**Comments**