Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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Person responsible for updating data

Contact
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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