

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 knee arthroplasty

Protocol summary

Study aim

In this study we are aiming to investigate the effect of the antioxidant agent including ascorbic acid on the amount of hidden blood loss in total knee arthroplasty (TKA).

Design

A double-blind randomized controlled trial with two parallel groups

Settings and conduct

In this randomized controlled clinical trial, 100 patients which are scheduled for TKA 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

Inclusion criterion: patients who are scheduled for total knee arthroplasty. Non-inclusion criteria: 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; diagnosis of inflammatory arthritis

Intervention groups

Intervention group: patients in this 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 10 mL) will be infused during the first 12 hour postoperative period. Control group: The patients in this group will receive only normal saline.

Main outcome variables

Total blood loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221104056393N1**

Registration date: **2023-06-27, 1402/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-27, 1402/04/06**

Update count: **0**

Registration date

2023-06-27, 1402/04/06

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

2023-06-18, 1402/03/28

Expected recruitment end date

2023-06-29, 1402/04/08

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 knee arthroplasty		Other design features	
Public title	The Effect of Ascorbic Acid on the blood loss in Total Knee Arthroplasty	Secondary Ids	empty
Purpose	Treatment	Ethics committees	
Inclusion/Exclusion criteria	Inclusion criteria: Candidates of total knee arthroplasty patients who provide written informed consent to be included in this study Exclusion criteria: history of thromboembolic events like deep vein thrombosis or pulmonary embolism history of cardiovascular disease like myocardial infarction or atrial fibrillation being in pregnancy or in the lactation period drug abusers or alcoholics severe renal dysfunction severe infection the preoperative hemoglobin less than 10 g/dL diagnosis of inflammatory arthritis like rheumatoid arthritis, pigmented villonodular synovitis and etc clotting disorders including abnormal PT, PTT or INR	1	
Age	No age limit	Ethics committee	
Gender	Both	Name of ethics committee	Ethics committee of Shahid Beheshti University of Medical Sciences
Phase	N/A	Street address	Azar dead end alley, Sharifi Manesh street., Pole Roomi, Tajrish
Groups that have been masked	- Participant - Outcome assessor	City	Tehran
Sample size	Target sample size: 100	Province	Tehran
Randomization (investigator's opinion)	Randomized	Postal code	1964714953
Randomization description	In this randomized controlled clinical trial, the patients will be consecutively and alternately (one in between) assigned into two groups in a 1:1 ratio.	Approval date	2023-06-14, 1402/03/24
Blinding (investigator's opinion)	Double blinded	Ethics committee reference number	IR.SBMU.RETECH.REC.1402.165
Blinding description	In this double-blind study, patients and the data collector are blinded. Patients are kept unaware of their group assignment and the intervention they are receiving. Patients in both groups receive serums with covers so that the content will not be visible to the patients. Both the treatment and control groups receive identical instructions and support. The data collector is kept blind to the group assignment of each patient. Collecting data including laboratory values after the surgery and clinical examinations will be performed without knowing the intervention done for the patient and only according to their records number.	Health conditions studied	
Placebo	Not used	1	
Assignment	Parallel	Description of health condition studied	Total Knee Arthroplasty
		ICD-10 code	M17.9
		ICD-10 code description	Osteoarthritis of knee, unspecified
		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

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

Category

Treatment - Surgery

2

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 10 mL) will be infused postoperatively during the first 12h.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Seyed Morteza Kazemi

Street address

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

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2200 1072

Email

pomonfared@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

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

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2200 1072

Email

boneresearch@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

Seyed Morteza Kazemi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

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

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2200 1072

Email

kazemimort@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Morteza Kazemi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

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

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2200 1072

Email

kazemimort@gmail.com

pomonfared@gmail.com

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Pooya Hosseini-Monfared

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

Orthopedics

Street address

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

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2200 1072

Email