

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation the effect of intravenous vitamin C injection during cesarean on the control of bleeding during cesarean and after that in pregnant women candidate for elective cesarean

Protocol summary

Study aim

Investigating the effect of vitamin C on the amount of bleeding during and after cesarean delivery

Design

A randomized clinical trial with the parallel groups, with control group, double-blind, phase 3 with 30 patients. The block randomization method will be designed by using "www.sealedenvelope.com"

Settings and conduct

This study will be conducted in Kamali Hospital on women scheduled for elective caesarean section. The purpose of this study is to investigate the effect of vitamin C on the amount of bleeding during and after cesarean delivery. Participants will be randomly divided into two groups: one (intravenous injection of vitamin C before cesarean section) and two (no intervention). The participants are aware of the type of intervention, the person who checks the outcome, the surgeon and the statistician are not aware of the type of intervention. The amount of bleeding during and after cesarean section, pain, duration of hospitalization and duration of surgery are compared between two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Candidate for elective cesarean section, age 45-17 Exclusion criteria: Emergency caesarean section, abnormal coagulation test results, Escorbic acid sensitivity , Eyperoxaluria, Creatinine more than 1.5 - UI, Having thalassemia, gout, cystinuria and G6PD deficiency , Oxalate kidney stones and Obesity

Intervention groups

Intervention group: two hours before induction of anesthesia, a vial of vitamin C is injected intravenously from Royan Daro Pharmaceutical Company. Control group: without the use of drugs and intervention

Main outcome variables

The amount of bleeding during and after cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221112056479N1**

Registration date: **2023-01-08, 1401/10/18**

Registration timing: **prospective**

Last update: **2023-01-08, 1401/10/18**

Update count: **0**

Registration date

2023-01-08, 1401/10/18

Registrant information

Name

Zeinab Amirpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3222 2021

Email address

z.amirpour1371@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of intravenous vitamin C injection during cesarean on the control of bleeding during cesarean and after that in pregnant women candidate for elective cesarean

Public title

Vitamin C in cesarean Effect of vitamin C in bleeding control of cesarean

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women candidates for elective cesarean section Age 17 to 45 years

Exclusion criteria:

Women who are prepared for caesarean section and other surgery at the same time Emergency caesarean section Abnormal coagulation test Escorbic acid sensitivity Epyperoxaluria Creatinine more than 1.5 - Ul Having thalassemia, gout, cystinuria, G6PD deficiency Oxalate kidney stones Obesity

Age

From **17 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of random allocation is block and the unit of randomization is individual. The blocked randomization list will be designed using www.sealedenvelope.com. The randomization list will be prepared by the statistician. The treatments will be placed in sealed envelopes according to the block randomization list, which will be kept by the ward nurse who is out of the study. After the patient's eligibility is determined, the procedure is explained to the patient and ethical consent is obtained. Then the nurse provides the envelope containing the type of treatment to the doctor, and the type of treatment is performed based on the treatment in the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistician will be unaware of the intervention method. Because of the type of intervention, the participants know about the type of intervention. Injections are performed by a person who is not part of the operating room staff. As a result, the surgeon and assistant surgeon and the person who records the final result of the study are unaware of the type of

intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Alborz University of Medical Sciences

Street address

Koi Karmandan North Kocheh 6th West Alley31

City

karaj

Province

Alborz

Postal code

3145746486

Approval date

2022-09-21, 1401/06/30

Ethics committee reference number

IR.ABZUMS.REC.1401.180

Health conditions studied

1

Description of health condition studied

Cesarean section

ICD-10 code

O82

ICD-10 code description

Encounter for cesarean delivery without indication

Primary outcomes

1

Description

Bleeding amount

Timepoint

During and 6 and 12 hours after surgery

Method of measurement

Gas number and hemoglobin number (quantitative and qualitative)

Secondary outcomes

1

Description

Pain score

Timepoint

12 hours after cesarean

Method of measurement

Visual analog scale

2

Description

Duration of cesarean section

Timepoint

Immediately after surgery

Method of measurement

Stopwatch

3

Description

Length of hospitalization

Timepoint

At the time of discharge from the hospital

Method of measurement

Patient file

Intervention groups

1

Description

Intervention group: two hours before induction of anesthesia, a vial of vitamin C is injected intravenously from Royan Daro Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Control group: without the use of drugs and intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Medical Teaching Hospital

Full name of responsible person

zeinab amirpour

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Shahada Square, Esfahani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

zeinab amirpour

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Taleghani Square, Taleghani BlvdAlborz Urinary
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Project implementer

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

zeinab amirpour

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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

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Full name of responsible person

Bahare khakifirouz

Position

Scientific committee

Latest degree

Specialist

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Position

Resident

Latest degree

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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

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