

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigating the effects of intravenous Vitamin C on stress response severity in prolonged preoperative fasting time in abdominal hysterectomy surgery

Protocol summary

Study aim

Determine the effect of vitamin C on the severity of stress responses following long-term fasting

Design

A double-blinded and randomized clinical trial with parallel groups design of 60 patients

Settings and conduct

This study will be performed as a double-blinded clinical trial at Al-Zahra Educational Center. In the treatment group, when the patient's fasting time is more than twelve hours, 1 gram of vitamin C will be injected into 500 milliliters of normal saline and will be infused in 20 minutes. In the control group, the same amount of normal saline will be injected in the serum. Anesthesiologist, the assessor, and the patients are unaware of type of treatment group. For all patients, general anesthetic method will be used with the same technique. All patients will be operated by one surgeon. In the last 15 minutes of surgery, 1 gram of paracetamol and 4 milligrams of Ondansetron will be infused for all patients. To measure the plasma level of CRP and glucose, the blood sample will be taken prior to infusion of vitamin C and 24 and 48 hours later. The length of stay in the hospital will also be recorded. Systolic and diastolic blood pressure and heart rate will be measured at the same times. Finally, results will be compared in two groups.

Participants/Inclusion and exclusion criteria

Entry Criteria: candidates of elective hysterectomy, between 35-65 years with a fasting time more than 12 hours. Non-entry criteria: patient dissatisfaction, hysterectomy in malignancy, accompanying surgery, patients under steroid therapy, endometriosis, diabetes

Intervention groups

group of vitamins C (500 milligrams in 5 milliliters), control group (5 milliliters normal saline) infused into 500 milliliters normal saline serum within 20 minutes.

Main outcome variables

Changes in plasma levels of CRP and blood glucose after vitamin C injection in patients with fasting time more than 12 hours

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130814014359N5**

Registration date: **2019-01-22, 1397/11/02**

Registration timing: **prospective**

Last update: **2019-01-22, 1397/11/02**

Update count: **0**

Registration date

2019-01-22, 1397/11/02

Registrant information

Name

Vally Imantalab

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1666 9064

Email address

vimantalab@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of intravenous Vitamin C on stress response severity in prolonged preoperative fasting time in abdominal hysterectomy surgery

Public title

The effect of vitamin C on stress intensity in long-term fasting

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients, candidate for elective abdominal hysterectomy
Age between 35-65 Fasting time, more than 12 hours

Exclusion criteria:

Patient dissatisfaction Hysterectomy in malignancy
Accompanying surgery Patients under treatment with steroids, including inflammatory and rheumatic diseases
endometriosis Diabetes type one and two Pelvic inflammatory diseases transfusion during surgery

Age

From **35 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized with quadruple blocks and divide into two groups of treatment and control. The randomization unit is individual. In this randomization, we do not have a layer and we use a random numbers table tool. After providing the list, we will give it to the anesthetic technician who is not a member of the research team, to categorize patients in control or treatment groups based on the list.

Blinding (investigator's opinion)

Double blinded

Blinding description

Vitamin C and placebo (normal saline) are prepared by an anesthetic technician who is not a member of this research group and will be coded in similar 5-millimeter syringes and will be given to the responsible anesthesiologist. By her, the drugs are injected into 500 ml of normal saline and will be infused within 20 minutes. In this study patients, the responsible anesthesiologist and the assessor are blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee Of Guilan University Of Medical Sciences

Street address

Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2018-12-29, 1397/10/08

Ethics committee reference number

IR.GUMS.REC.1397.379

Health conditions studied**1****Description of health condition studied**

Stress responses in prolonged preoperative fasting In abdominal hysterectomy surgery

ICD-10 code

F43

ICD-10 code description

Reaction to severe stress, and adjustment disorders

Primary outcomes**1****Description**

Changes in CRP factor levels in blood

Timepoint

Prior to infusion of vitamin C, 24 and 48 hours after surgery

Method of measurement

Taking blood sample

2**Description**

Changes glucose levels in blood

Timepoint

Prior to infusion of vitamin C, 24 and 48 hours after

surgery
Method of measurement
Taking blood sample

Secondary outcomes

1

Description

Systolic and diastolic blood pressure changes

Timepoint

Prior to infusion of vitamin C, 24, 48 hours after surgery

Method of measurement

Measuring the patient's blood pressure

2

Description

Changes in heart rate

Timepoint

Prior to infusion of vitamin C, 24, 48 hours after surgery

Method of measurement

Getting the patient's pulse

3

Description

Duration of staying in the hospital

Timepoint

discharge day

Method of measurement

Number of days in hospital

Intervention groups

1

Description

Intervention group: The vitamin C group: when the patient's fasting time is about twelve hours, one gram vitamin C (500 milligrams in 5 milliliters, manufactured by Osveh Pharmaceutical Company) will be injected into 500-milliliter normal saline serum and infused within 20 minutes.

Category

Prevention

2

Description

Control group: placebo group: 5 milliliters of normal saline will be injected into 500-milliliter normal saline serum and infused within 20 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital
Full name of responsible person
Dr Gelareh Biazar
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Namjoo Street
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Web page address
<http://www.gums.ac.ir/azzahra>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht 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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Vali Imantalab

Position

Associate Professor of Cardiac Anesthesiology

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Position

Research Expert/(MSc) English

Latest degree

Master

Other areas of specialty/work

Nursery

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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

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

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