Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of vitamin C and vitamin E administration on pain and TNF-α serum level in patients undergoing major surgery with general anesthesia

Protocol summary

Study aim
The aim of this study is to compare the effect of using vitamin C and vitamin E on prevention of pain and increased serum TNF-α levels in major surgery.

Design
Community-based, applied, randomized, triple-blind controlled clinical trial with parallel groups design

Settings and conduct
The study population consisted of 150 patients referring to Shahrekord Ayatollah Kashani hospital, who were candidate for major surgery lasting longer than an hour (Including: open prostatectomy, hysterectomy, cystichema and cholecystectomy) and were selected by convenience sampling.

Participants/Inclusion and exclusion criteria
Inclusion criteria were being candidate for major surgery lasting longer than an hour (including: open prostatectomy, hysterectomy, cystichema and cholecystectomy) and the ASA physical status classes 1 and 2. In addition, prohibition of general anesthesia in patients; history of taking any supplements or antioxidants before surgery such as vitamin C and vitamin E; and a history of taking any medication that interferes with the oxidant or antioxidant agents prevented from being enrolled in the study.

Intervention groups
Patients were divided into three groups of 50 each by convenience random allocation, and each group separartely received 2 grams of vitamin C, 400 units of vitamin E and placebo tablets, 48 hours before anesthesia induction. Blood samples are taken to determine the serum TNF-α level 12 hours before induction and 6 hours after the completion of surgery. The pain level was measured by the Visual Analog Scale (VAS).

Main outcome variables
Severity of pain; serum TNF-α levels; Level of coagulation factors (BT, PT, PTT, INR levels)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110514006480N15**
Registration date: **2018-07-08, 1397/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-08, 1397/04/17**
Update count: **0**

Registration date
2018-07-08, 1397/04/17

Registrant information

Name
Mohammad Taghi Moradi

Name of organization / entity
Shahrekord University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-06, 1397/04/15

Expected recruitment end date
2018-11-06, 1397/08/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of vitamin C and vitamin E administration on pain and TNF-α serum level in patients undergoing major surgery with general anesthesia

Public title

Effect of Vit C and Vit E on pain and TNF-α serum level in major surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients candidate for major surgery, longer than an hour (Including: open prostatectomy, hysterectomy, cystichema and cholecystectomy) The ASA physical status classification system in one or two classes

Exclusion criteria:

Prohibition of general anesthesia in patients History of taking any supplements or antioxidants before surgery such as vitamin C and vitamin E A history of taking any medication that interferes with the oxidant or antioxidant agents

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into three groups by simple random sampling and Using three categories of cards that listed on them the letters A, B and C

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, considering that medications are given to patients as pills; the patient is not aware of the type of medicine And only clinical nurse knows the groups and identifies them with groups A, B and C. Researcher and data analyzer also checks the groups with the names A, B, and C.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Ayatollah Kashani Street

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Approval date

2017-04-30, 1396/02/10

Ethics committee reference number

IR.SKUMS.REC.1395.325

Health conditions studied

1

Description of health condition studied

major surgery

ICD-10 code

Z92.4

ICD-10 code description

Personal history of major surgery

Primary outcomes

1

Description

Severity of pain

Timepoint

Before the intervention, 6 hours after the completion of the surgery

Method of measurement

Visual analog scale

2

Description

serum TNF-α levels

Timepoint

Before the intervention, 6 hours after the completion of the surgery

Method of measurement

ELISA Kit

Secondary outcomes

1

Description
Prothrombin Time
Timepoint
Before the intervention, 6 hours after the completion of the surgery
Method of measurement
Prothrombin Time Test

2

Description
Partial Thromboplastin Time
Timepoint
Before the intervention, 6 hours after the completion of the surgery
Method of measurement
Partial Thromboplastin Time Test

3

Description
International Normalized Ratio
Timepoint
Before the intervention, 6 hours after the completion of the surgery
Method of measurement
International Normalized Ratio Test

4

Description
Bleeding Time
Timepoint
Before the intervention, 6 hours after the completion of the surgery
Method of measurement
Bleeding Time Test

Intervention groups

1

Description
Intervention group 1: Forty eight hours before anesthesia, 2 grams of vitamin C is prescribed.
Category
Treatment - Drugs

2

Description
Intervention group: Forty eight hours before anesthesia, 400 IU of vitamin E is prescribed.
Category
Treatment - Drugs

3

Description
Control group: Forty eight hours before anesthesia, Placebo pill (containing starch compound) is prescribed.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Kashani hospital in Shahr-e-kord
Full name of responsible person
Ebrahim Poryamofrad
Street address
Ayatollah Kashani hospital, Parastar Ave, Shahrekord
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Shahrekord
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Chahar-Mahal-va-Bakhtiari
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https://kashanihp.skums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr. Seyed Kamal Solati
Street address
Deputy of Research and Technology, Shahrekord University of Medical Sciences, Ayatollah kashani Blvd., Shaharekord
City
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Chahar-Mahal-va-Bakhtiari
Postal code
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Phone
+98 38 3334 2414
Email
kamal_solati@yahoo.com
Grant name
Grant code / Reference number
2405
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Ebrahim PouryaMofrad
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Department, Kashani hospital, Parastar Ave, Shahrekord
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Person responsible for updating data

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rahim2019@yahoo.com
Web page address

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