

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effect of vitamin C and vitamin E administration on pain and TNF- $\alpha$ 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- $\alpha$  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 separately 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- $\alpha$  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- $\alpha$  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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 1334 9509

##### Email address

mtmoradi@skums.ac.ir

##### 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- $\alpha$  serum level in patients undergoing major surgery with general anesthesia

**Public title**  
Effect of Vit C and Vit E on pain and TNF- $\alpha$  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, cysticema 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- $\alpha$  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

#### City

Shahrekord

#### Province

Chahar-Mahal-va-Bakhtiari

#### Postal code

۸۸۱۶۷۵۸۹۱۵

#### Phone

+98 38 3226 4825

#### Fax

+98 38 3222 8600

#### Email

rahim2019@yahoo.com

#### Web page address

<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

Shahrekord

#### Province

Chahar-Mahal-va-Bakhtiari

#### Postal code

۸۸۱۵۷۱۳۴۷۱

#### 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

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

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

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**Province**

Chahar-Mahal-va-Bakhtiari

**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