

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Comparing the effect of Amino acids infusion with placebo to prevent postoperative shivering in women aged from 20 to 50 years old undergoing Laparoscopic Cholecystectomy

#### Protocol summary

##### Summary

The aim of this study is to evaluate the effect of intravenous Amino acids to prevent postoperative shivering in women undergoing Laparoscopic Cholecystectomy. This is a randomized controlled clinical trial that will perform on 80 female patients aged from 20-50 years old undergoing Laparoscopic Cholecystectomy in Velayat hospital of Qazvin. In this study, patients are in ASA class I and II. This is a double blind study (physicians and patients are not aware that how the distribution of infusion is). Patients were randomly divided into two groups on the basis of selection of colored cards. Before induction of anesthesia, heart rate, blood pressure, arterial oxygen saturation and oral temperature of patients will be measured and recorded in both groups. General anesthesia will be performed for all patients with similar method. Immediately after induction of anesthesia, control group will receive normal Saline infusion (placebo) and case group will receive Amino acid infusion 10% (2ml/kg/h maximum 1mg/kg) for each patient until the end of surgery. After entering the recovery heart rate, blood pressure, arterial oxygen saturation, oral temperature, and postoperative shivering (by clinical observation and on the basis of a similar grading system) will be recorded at 10, 20 and 30 minutes. The Case group and control group will be compared with each other in the end.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016010925676N2**

Registration date: **2016-05-11, 1395/02/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-11, 1395/02/22

##### Registrant information

###### Name

Hamid Kayalha

###### Name of organization / entity

Qazvin University of Medical Sciences & Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3332 1007

###### Email address

hkayalha@qums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for research Qazvin University of Medical Sciences

##### Expected recruitment start date

2015-07-13, 1394/04/22

##### Expected recruitment end date

2015-12-13, 1394/09/22

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of Amino acids infusion with placebo to prevent postoperative shivering in women aged from 20 to 50 years old undergoing Laparoscopic Cholecystectomy

## Public title

The effect of amino acids in the prevention of postoperative shivering

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Female patients aged from 20 to 50 years old; patients with ASA class I and II having elective laparoscopic cholecystectomy; consent to participate up to the end of study. Exclusion criteria: Patients with ASA class more than 2; Using Corticosteroids or No steroidal anti-inflammatory drugs(NSAID); body temperature more than 38 and less than 36.3 centigrade degrees; sensitivity to amino acids; obesity; surgery duration less than 1.5 or more than 2.5 hour; Hemodynamic changes more than 20%; prescribing blood or blood products during surgery.

## Age

From **20 years** old to **50 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of the University of Medical Sciences

##### Street address

Shahid Bahonar Blvd, Qazvin.

##### City

Qazvin

##### Postal code

3419759811

#### Approval date

2015-12-09, 1394/09/18

#### Ethics committee reference number

IR.QUMS.REC.1394.217

## Health conditions studied

### 1

#### Description of health condition studied

Postoperative shivering

#### ICD-10 code

T88.9

#### ICD-10 code description

Complication of surgical and medical care, unspecified

## Primary outcomes

### 1

#### Description

Postoperative shivering

#### Timepoint

After entering the recovery, every 10 min to 30 min

#### Method of measurement

Clinical observation

### 2

#### Description

Arterial oxygen saturation

#### Timepoint

After entering the recovery, every 10 min until 30 min

#### Method of measurement

By monitoring devise

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Immediately after induction of anesthesia, infusion of Amino acid 10% (2ml/kg/h maximum 1mg/kg) will begin for each of the patients in the case group, and will continue until the end of surgery.

#### Category

Prevention

### 2

#### Description

Immediately after induction of anesthesia, infusion of saline began for each of the patients in the control group (C) and were continued until the end of surgery.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Velayat educational and treatment center

**Full name of responsible person**

Dr. Mohammad qasem Roshanfekar Belalami

**Street address**

Velayat Hospital, Taavon Sq., 22 Bahaman Blvd,  
Elahieh

**City**

Qazvin

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research Qazvin University of  
Medical Sciences

**Full name of responsible person**

Dr. Taghi Naserpour

**Street address**

Shahid Bahonar avenue, Qazvin.

**City**

Qazvin

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for research Qazvin University of Medical  
Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Qasem Roshanfekar Belalami

**Position**

Anesthesiologist

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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Dr. Hamid Kayalha

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Assistant Professor of Anesthesiology

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## Person responsible for updating data

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Dr. Tahereh Mahmudi

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*