

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

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Name of organization / entity

Qazvin University of Medical Sciences & Health Services

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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

Contact

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Assistant Professor of Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Tahereh Mahmudi

Position

Assistant of Anesthesiology

Other areas of specialty/work

Street address

City

Qazvin

Postal code

Phone

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Fax

Email

Web page address

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