# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jul 2026

## The effect of early oral nutrition on decreasing the complications and hospitalization duration following laparoscopic cholecystectomy surgery

## Protocol summary

**Summary**

The main aim of this study is to evaluate the effect of early oral nutrition on decreasing the complications and hospitalization duration following laparoscopic cholecystectomy surgery. The study is a single-centre, randomized interventional clinical trial in which, 100 patients who are candidate for laparoscopic cholecystectomy at Imam Khomeini hospital of Ardabil in 2016-17 are randomly allocated into two equal groups of intervention and control. Inclusion criteria are as follows: persons undergoing laparoscopic cholecystectomy, aged 15 years old or older, consent to the study, and no associated malnutrition. Exclusion criteria are as follows: Age less than 15 years, associated malnutrition, severe associated diseases, and emergent cases. The studied intervention is initiation of post-operative oral nutrition. The oral nutrition is initiated 1 hour after full recovery of patients from anesthesia in the intervention group and after 24 hours of surgery in the control group. The study outcomes are vomiting, nausea, hearing of bowel sound, flatus passing, stools passing, and duration of admission.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017081434660N1**
Registration date: **2017-09-04, 1396/06/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2017-09-04, 1396/06/13

**Registrant information**

**Name**

Masoud Nourani

**Name of organization / entity**

Ardabil University Of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Deputy of research, Ardabil medical university, Ardabil

**Expected recruitment start date**

2016-07-22, 1395/05/01

**Expected recruitment end date**

2017-07-23, 1396/05/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of early oral nutrition on decreasing the complications and hospitalization duration following laparoscopic cholecystectomy surgery

**Public title**

The effect of early oral nutrition on decreasing the complications and hospitalization duration following laparoscopic cholecystectomy surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: persons undergoing laparoscopic cholecystectomy; aged older than 15 years; consent to the study; and no associated malnutrition. Exclusion criteria: Age less than 15 years; associated malnutrition; severe associated diseases; and emergent cases.

**Age**
From **15 years** old to **75 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **100**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethic Committee Of Ardabil University Of Medical Sciences
**Street address**
Ardabil Complex Univesity, Daneshgah st., Ardabil, Ardabil Province.
**City**
Ardabil
**Postal code**
5615751147
**Approval date**
2017-03-05, 1395/12/15
**Ethics committee reference number**
IR.ARUMS. REC.1395.133

## Health conditions studied

### 1

**Description of health condition studied**
laparoscopic cholecystectomy
**ICD-10 code**
K80.1
**ICD-10 code description**
Calculus of gallbladder with other cholecystitis

## Primary outcomes

### 1

**Description**
nausea
**Timepoint**
every 6 hours until hospital discharge of patients
**Method of measurement**
Asking from patients

### 2

**Description**
vomiting
**Timepoint**
every 6 hours until hospital discharge of patients
**Method of measurement**
Asking from patients

### 3

**Description**
hearing of bowel sound
**Timepoint**
Every hour
**Method of measurement**
Hearing of bowel sound by stetoscope

### 4

**Description**
flatus passing
**Timepoint**
every 1 hour
**Method of measurement**
Asking from patients

### 5

**Description**
stools passing
**Timepoint**
every 1 hour
**Method of measurement**
Asking from patients

### 6

**Description**
duration of admission
**Timepoint**
after hospital discharge of patients
**Method of measurement**
Days of hospitalization

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Initiation of oral nutrition 1 hour after

full recovery of patient from anesthesia

**Category**

Treatment - Other

**2**

**Description**

Control group: Initiation of oral nutrition 24 hours after surgery

**Category**

Treatment - Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital of Ardabil City

**Full name of responsible person**

Masoud Nourani

**Street address**

Imam Khomeini Hospital , Ataee St, Ardabil

**City**

Ardabil

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Ardabil University of Medical Sciences

**Full name of responsible person**

Dr Hadi Piri Dogahe

**Street address**

Ardabil Complex Univesity, Daneshgah st., Ardabil, Ardabil Province.

**City**

Ardabil

**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, Ardabil 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**

Ardabil University Of Medical Sciences

**Full name of responsible person**

Masoud Nourani

**Position**

Medical student

**Other areas of specialty/work**

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**Web page address**

## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

Saeid Sadeghieh Ahari

**Position**

Associate Professor/ Public Health

**Other areas of specialty/work**

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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*