Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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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Person responsible for scientific inquiries

Contact

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Associate Professor/ Public Health

Other areas of specialty/work

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Person responsible for updating data

Contact

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Masoud Nourani

Position

Medical Student

Other areas of specialty/work

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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