

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the Necessity of Gastric Endoscopy Before Cholecystectomy in Patients with Gallstones

Protocol summary

Study aim

Determination of clinical manifestations observed in patients with upper gastrointestinal endoscopy (except gallstones) Determination of improvement in gastrointestinal pain and symptoms after cholecystectomy in patients with normal upper gastrointestinal endoscopy Determination of improvement in gastrointestinal pain and symptoms after cholecystectomy in patients with abnormal upper gastrointestinal endoscopy

Design

Clinical trial without control group, with parallel groups, not blinded on 30 patients, randomization of rand function of Excel software

Settings and conduct

Study in Khatam Al-Nabiah Hospital in Shahroud and endoscopy of 30 gallstone patients 2 days before cholecystectomy and evaluation of symptoms one week, three weeks and three months after cholecystectomy

Participants/Inclusion and exclusion criteria

Admission: Age over 18 years, patients with gallstones
No admission: age under 18, unstable clinical condition, patients with acute abdomen, patients with gallbladder neoplasia

Intervention groups

Perform gastric endoscopy two days before cholecystectomy

Main outcome variables

Reduction of cholecystectomy surgery in patients with gastric lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210224050486N1**

Registration date: **2021-03-03, 1399/12/13**

Registration timing: **retrospective**

Last update: **2021-03-03, 1399/12/13**

Update count: **0**

Registration date

2021-03-03, 1399/12/13

Registrant information

Name

Akam Amini

Name of organization / entity

The azad university of shahrood

Country

Iran (Islamic Republic of)

Phone

+98 44 4623 9247

Email address

lordakam095@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-11-27, 1398/09/06

Actual recruitment start date

2019-10-07, 1398/07/15

Actual recruitment end date

2020-01-06, 1398/10/16

Trial completion date

2020-05-15, 1399/02/26

Scientific title

Evaluation of the Necessity of Gastric Endoscopy Before Cholecystectomy in Patients with Gallstones

Public title

The Necessity of Gastric Endoscopy Before Cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Ultrasonographic diagnosis of symptomatic gallstones

Exclusion criteria:

Dissatisfaction with participating in the study Age under 18 years Patients with acute abdomen Patients with unstable general condition Patients with gallbladder neoplasia

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University - Shahroud Branch

Street address

Semnan , Shahroud , University Boulevard , Next to the gas station , Islamic Azad University , Central Building

City

Shahroud

Province

Semnan

Postal code

3614871151

Approval date

2021-01-13, 1399/10/24

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1399.070

Health conditions studied**1****Description of health condition studied**

Gallstone , Gastric mucosal lesions

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Findings observed in gastric endoscopy

Timepoint

Perform gastric endoscopy 2 days before cholecystectomy

Method of measurement

Gastric endoscopy device

Secondary outcomes**1****Description**

Measurement of epigastric pain, heartburn, nausea, vomiting and reflux

Timepoint

The day after cholecystectomy and 7 days and 21 days and 90 days after cholecystectomy

Method of measurement

questionnaire

Intervention groups**1****Description**

Intervention group: Intervention group: In this study, we included 30 patients who were admitted to the general surgery ward of Khatam al-Anbia Hospital in Shahroud with a diagnosis of gallstones. One or two days before gallstone surgery for all patients, upper gastrointestinal endoscopy was performed. Clinical manifestations observed in upper gastrointestinal endoscopy (gastric ulcer, GERD, gastritis, duodenal ulcer, esophagitis, duodenal inflammation) were recorded. The frequency of pathological conditions other than gallstones found by endoscopic method is considered. Based on the pathological conditions found in endoscopy or the absence of pathological conditions, patients were divided into normal and abnormal groups .Evaluation of the improvement of patients' symptoms such as epigastric pain (vas pain scale from one to ten), nausea and vomiting (yes, no), indigestion (yes, no), or reflux (yes / no). In patients in two groups with normal endoscopy and Abnormalities were performed at the following times: before surgery, one week after surgery, three weeks after surgery, three months after surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahroud , Khatam Al-Anbia Hospital

Full name of responsible person

Mehdi Naghavi

Street address

Khatam Al-Anbia Hospital, University Blvd., Tehran St.

City

Shahroud

Province

Semnan

Postal code

3614871151

Phone

+98 23 3239 2661

Fax**Email**

mehdinaghavimd@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mehdi Naghavi

Street address

Shahroud, Tehran St., Nader Boulevard, Unit 10

City

Shahroud

Province

Semnan

Postal code

3615653164

Phone

+98 44 4623 9247

Email

lordakam095@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Mehdi naghavi

Position

Assistant Professor , Specialist Physician, Faculty

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Semnan, Shahroud, Tehran St., University Blvd.,
Khatam Al-Anbia Hospital

City

Shahroud

Province

Semnan

Postal code

3614871151

Phone

+98 23 3239 2661

Email

mehdinaghavi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mehdi Naghavi

Position

Assistant Professor, Faculty Physician ,Phd

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Shahroud, Tehran St., University Blvd., Khatam Al-
Anbia Hospital

City

Shadroud

Province

Semnan

Postal code

3615871151

Phone

+98 23 3239 2661

Email

Mehdinaghavimd@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Akam Amini

Position

Entern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Buchan, Baharestan St., Soma Boulevard, No. 10

City

Boukan

Province

West Azarbaijan

Postal code

5943159591

Phone

+98 44 4623 9247

Email

Lordakam095@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

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