

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the efficacy of ursodeoxycholic acid therapy in patients with acute cholecystitis who are candidates for delayed cholecystectomy in Ayatollah Mousavi Hospital in Zanzan

Protocol summary

Study aim

Evaluation of the effect of ursodeoxycholic acid in reducing pain in patients with acute cholecystitis who are candidates for delayed cholecystectomy

Design

The study will be divided into two groups (intervention and control). Each group's size will be 30 patients—randomization will be done by statistical software with the random blocks method. The study is a phase 3 clinical trial that will be performed on 60 patients.

Settings and conduct

Patients admitted to Ayatollah Mousavi Hospital in Zanzan after being diagnosed with cholecystitis and candidate for delayed cholecystectomy, will be divided into two groups. Prescription drugs will be different for patients. Data on the patient's pain will be collected with a Visual Analog Scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with a diagnosis of acute cholecystitis and a candidate for delayed surgery (patients who did not present in the first 72 hours of the disease, medical problems such as severe chronic heart failure). Stone size less than 15 mm, patients with mild symptoms or asymptomatic. Exclusion criteria: Patients who are unable to tolerate ursodeoxycholic acid, patients who become candidates for emergency or elective surgery before the sixth week during the prevention period. Age under 18 years, patients with moderate to severe symptoms, patients with complicated and complicated gallstones, patients with jaundice, patients with accompanying cholangitis, patients with impaired liver tests

Intervention groups

Patients with acute cholecystitis who are candidates for delayed surgery are included in the study. Treatment will be performed in two groups with ursodeoxycholic acid

and placebo.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210309050650N1**

Registration date: **2021-03-29, 1400/01/09**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-29, 1400/01/09**

Update count: **0**

Registration date

2021-03-29, 1400/01/09

Registrant information

Name

Naser Keikhali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 1851

Email address

nkeikhali@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of ursodeoxycholic acid therapy in patients with acute cholecystitis who are candidates for delayed cholecystectomy in Ayatollah Mousavi Hospital in Zanjan

Public title

The efficacy of ursodeoxycholic acid therapy in delay cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient diagnosed with acute cholecystitis and candidate for delayed surgery (patients who did not present within the first 72 hours of onset) Patients who are not candidates for early surgery due to other medical problems such as severe congestive heart failure. Patient's personal consent to attend the study Stone size less than 15 mm Patients with mild symptoms or asymptomatic

Exclusion criteria:

Patients who are unable to tolerate ursodeoxycholic acid Patients with complicated gallstones Patients with cholangitis Patients with impaired liver tests Patients with moderate to severe symptoms Patients who become candidates for emergency surgery before the sixth week during the waiting period.

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

A randomized block is used to randomize the patients under study and to fully observe the randomness of placement in the control group and the sample group because the inclusion process requires randomization due to the ongoing recruitment. Based on the calculated sample size, the sample size in each group is 24 people for easier application of random blocks to randomize the members of each group. Permutations are considered as 6 permutations according to 2 groups: AABB, ABAB, BBAA, BABA, BAAB, ABBA. The permutations are written on 6 cards and the selection of permutations and their order will be randomly selected from among the cards. The order of exit of the cards is written and will determine the order of recruitment of intervention groups based on it. An individual randomization unit will be used for the study. The information of the registered

persons will be anonymous and without their personal information.

Blinding (investigator's opinion)

Not 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 Zanjan University of Medical Science

Street address

Ayatollah Mousavi Hospital, Zanjan

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Zanjan

Province

Zanjan

Postal code

4513956183

Approval date

2020-11-27, 1399/09/07

Ethics committee reference number

IR.ZUMS.REC.1399.231

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

Acute Cholecystitis

ICD-10 code

K81.0

ICD-10 code description

Acute cholecystitis

Primary outcomes**1****Description**

Patients' pain while waiting for cholecystectomy surgery

Timepoint

Patients' pain will be assessed at baseline and at 3 and 6 weeks after starting treatment.

Method of measurement

Based on Visual Analogue Scale scale, data would be collected.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ursodeoxycholic acid tablets with a dose of 9-10 mg/kg produced by Exir Pharmacy, will be taken orally at bedtime once a day. The duration of treatment is six weeks.

Category

Treatment - Drugs

2

Description

Control group: A placebo with the same appearance as the drug of the intervention group will be provided by a similar pharmaceutical company (Exir Pharmacy) and does not contain any active substance. It will be taken once a day, orally and at bedtime. The duration of treatment will be 6 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Naser Keikhali

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Zanjan University of Medical Sciences

Full name of responsible person

Naser Keikhali

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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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

Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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