

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the effectiveness of enoxaparin in preventing the occurrence of deep vein thrombosis in patients' candidates for laparoscopic cholecystectomy

Protocol summary

Study aim

Determining the effectiveness of enoxaparin in preventing deep vein thrombosis in patients undergoing laparoscopic cholecystectomy

Design

A clinical trial with a control group, community-based and pragmatic, With parallel groups, randomized

Settings and conduct

The eligible patients who hospitalized in surgical wards of Ayatollah Mousavi Hospital will be included in the study. for both groups, half an hour prior to laparoscopic cholecystectomy (LC), routine treatments will be administered. in addition to it in intervention group, half an hour before LC operation , enoxaparin will be injected subcutaneously. The enoxaparin effectiveness will be measured 24 hours, 72 hours and 14 days following the injection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Willingness to participate in the study 2-All patients under 70 years of age do not have coagulation disorders 3-Not having of underlying diseases associated with DVT 4-All patients have symptomatic gallstones (abdominal pain, nausea and vomiting after eating) 5- Simultaneous existence of gallbladder polyps and gallstones 6- Diabetic people with gallstones 7- Patients with asymptomatic gallstones who are unable to access equipped centers in the future 8- Patients who have not allergy to enoxaparin 9- Do not take anti-coagulant drugs. exclusion criteria: 1-Patients with surgical indications with the possibility of absolute rest after surgery 2-Patients with the possibility of complications such as postoperative bleeding

Intervention groups

Intervention group: In addition to routine treatments, injectable enoxaparin, made by Alborz Drug Company, 4000 units, single dose, half an hour before surgery, in the operating room, will be injected subcutaneously for

these patients. Control group: will receive only routine treatments.

Main outcome variables

Absence of deep vein thrombosis, absence of pulmonary embolism

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210602051484N1**

Registration date: **2021-08-10, 1400/05/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-10, 1400/05/19**

Update count: **0**

Registration date

2021-08-10, 1400/05/19

Registrant information

Name

Mohammad Mohammadi Arbati

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 24 3313 0000

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mohammadarbati@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-20, 1400/03/30

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of enoxaparin in preventing the occurrence of deep vein thrombosis in patients' candidates for laparoscopic cholecystectomy

Public title

The effectiveness of enoxaparin in preventing deep vein thrombosis

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study All patients under 70 years of age do not have coagulation disorders Not having underlying diseases associated with DVT All patients have symptomatic gallstones (abdominal pain, nausea and vomiting after eating) Simultaneous existence of gallbladder polyps and gallstones Diabetic people with gallstones Patients with asymptomatic gallstones who are unable to access equipped centers in the future. Patients who have not allergy to enoxaparin. Do not take anti-coagulant drugs

Exclusion criteria:

Patients with surgical indications with the possibility of absolute rest after surgery Patients with the possibility of complications such as postoperative bleeding

Age

To **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected from 200 patients admitted to the surgical wards of Ayatollah Mousavi Hospital affiliated to Zanjan University of Medical Sciences. The samples were divided into 100 subjects in the intervention group and 100 subjects in the control group by simple random method using coin toss. In coin tossing, if the coin image part came, the samples were in the intervention group and otherwise the samples were in the control group. Sampling was continued until the number of samples in each group was completed.

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**

Ethics Committee of Deputy of Research and Technology of Zanjan University of Medical Sciences

Street address

Deputy of Research and Technology, third floor, Second building, Central Headquarters of Zanjan University of Medical Sciences, The beginning of Jomhuri Eslami Boulevard, Azadi Blv, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2021-06-08, 1400/03/18

Ethics committee reference number

IR.ZUMS.REC.1400.091

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

Deep vein thrombosis

ICD-10 code

I80.2

ICD-10 code description

Phlebitis and thrombophlebitis of other deep vessels of lower extremities

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

Not occurrence of deep vein thrombosis

Timepoint

The effectiveness of enoxaparin in 24 hours after injection, 72 hours after injection and 14 days after injection

Method of measurement

Presence or absence of deep vein thrombosis examination and follow-up with color Doppler ultrasound and entering its information in a checklist

2**Description**

Not occurrence of pulmonary embolism

Timepoint

The effectiveness of enoxaparin in 24 hours after injection, 72 hours after injection and 14 days after injection

Method of measurement

Presence or absence of pulmonary embolism by examination and follow-up with CT pulmonary angiography with venous contrast and entering its information in a checklist

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, in addition to routine treatments, injectable enoxaparin 4000 units, made by Alborz Drug Company, single dose, half an hour before surgery, in the operating room, will be injected subcutaneously for these patients.

Category

Prevention

2

Description

Control group: will receive only routine treatments including daily dressings and antibiotics.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Dr Mohammad Mohammadiarbati

Street address

Ayatollah Mousavi Hospital, Gavazang Street, Soboti Blv, Zanzan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanzan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

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Vice chancellor for research, Zanzan University of Medical Sciences, Azadi Blvd. Zanzan

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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

Zanzan 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

Zanzan University of Medical Sciences

Full name of responsible person

Dr Mohammad Mohammadiarbati

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After completing the study, there is a plan to share non-identifiable individual data of the participants, the study protocol, the statistical analysis of the data, the informed consent form patents, clinical reports, analysis codes, and data coding systems (Dictionary).

When the data will become available and for how long

The start of the access period to the data of this study will be from Early 2022 and approximately 6 months after the publication of the results.

To whom data/document is available

The data of this study are possible for all patients with gallstones and surgical candida, and especially those working in health care systems.

Under which criteria data/document could be used

The researcher wants to use the data to improve gallstone patients and candidates for surgery.

From where data/document is obtainable

To receive information anyone can be use the following email: mohammadarbati@zums.ac.ir

What processes are involved for a request to access data/document

After sending the message and introducing herself or himself and the reason for the need for data, the applicant will be provided with the information after confirmation.

Comments