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 Ayatolllah 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 study2-All patients under 70 years of age do not have coagulation disorders3-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)

Phone
+98 24 3313 0000

Email address
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
Ayatolllah Mousavi Hospital, Gavazang Street, Soboti Blv, Zanjan, Iran

City
Zanjan

Province
Zanjan

Postal code
4513956183

Phone
+98 24 3313 0000

Fax
+98 24 3313 1203

Email
Mousavihospital@zums.ac.ir

Web page address
http://zums.ac.ir/index.php?slc_lang=fa&sid=19

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Dr. Alireza Shoghli

Street address
Vice chancellor for research, Zanjan University of Medical Sciences, Azadi Blvd. Zanjan

City
Zanjan

Province
Zanjan

Postal code
45154

Phone
+98 24 3315 6477

Fax
+98 24 3315 6770

Email
Research@zums.ac.ir

Web page address
http://zums.ac.ir/index.php?slc_lang=fa&sid=3

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
Dr Mohammad Mohammadiarbati

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
General Surgery

Street address
Ayatollah Mousavi Hospital, Gavazang Street,Pro. Soboti Blv, Zanjan, Iran

City

Zanjan
Province
Zanjan
Postal code
4513956183
Phone
009833130000
Fax
+98 24 3313 1203
Email
mohammadarbati@zums.ac.ir
Web page address
http://zums.ac.ir/index.php?slc_lang=fa&sid=19

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zanjan 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
Street address
Ayatollah Mousavi hospital, Gavazang Street, Pro. Soboti Blv, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4513956183
Phone
+98 24 3313 0000
Fax
+98 24 3313 1203
Email
mohammadarbati@zums.ac.ir
Web page address
http://zums.ac.ir/index.php?slc_lang=fa&sid=19

Person responsible for updating data

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr Babak Haj Ghahramani Fard
Position
General Surgery Student
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Ayatollah Mousavi hospital, Gavazang Street, Pro. Soboti Blv, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4513956183
Phone
009833130000
Fax
+98 24 3313 1203
Email
babakhajghahremani@gmail.com
Web page address
http://zums.ac.ir/index.php?slc_lang=fa&sid=19

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