

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial of evaluation of effect of Enoxaparin and Aspirin in portal, splenic, and superior mesenteric vein thrombosis after open splenectomy

Protocol summary

Summary

This study will be designed to investigate the effects of Enoxaparin and Aspirin in preventing portal system venous thrombosis in patients undergoing open Splenectomy. This study will be conducted as a single-blind randomized clinical trial. The study population will be selected from all patients who undergoing open Splenectomy for any reason. The aim of the study and implementation of the procedure will be explained to them. Once patients are satisfied, written informed consent will be provided and they will be enrolled. Inclusion criteria including to undergoing open splenectomy surgery. Exclusion criteria including: lack of cooperation from the patient to provide the ultrasonography; died of disease; and a history of venous thrombosis. Patients Blocks will assigned randomly to two groups of intervention and control. In the intervention group for five days after the operation 40 mg Enoxaparin will be administered daily subcutaneously and Then for a month 100 mg Aspirin tablets will be prescribed daily and then Color Doppler Ultrasonography of thrombosis of portal and splenic and superior mesenteric vein will be provided within a week. In the control group, a month after the surgery without administering prophylaxis, Color Doppler Ultrasonography of thrombosis of portal and splenic and superior mesenteric vein will be provided and the results will be recorded and Finally, the two groups will be compared with each other.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016042527600N1**

Registration date: **2016-06-12, 1395/03/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-12, 1395/03/23

Registrant information

Name

Mosayeb Rafieepour

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of evaluation of effect of Enoxaparin and Aspirin in portal, splenic, and superior mesenteric vein thrombosis after open splenectomy

Public title

The effect of Enoxaparin and Aspirin for the prevention of thrombosis after open splenectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Patients who underwent open Splenectomy for any reason from 21 may 2015 to 22 may 2016 in Golestan Hospital, Ahvaz, Iran Exclusion Criteria: Uncooperative patients to ultrasound follow up; Patients' death; A history of venous thrombosis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 126

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will be done as blocking methods.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Science

Street address

Esfand street, Farvardin Street, Golestan, Ahvaz

City

Ahvaz

Postal code

Approval date

2015-01-23, 1393/11/03

Ethics committee reference number

lr.ajums.rec.1394.738

Health conditions studied

1

Description of health condition studied

open splenectomy

ICD-10 code

D73.9

ICD-10 code description

Disease of spleen, unspecified

Primary outcomes

1

Description

Thrombosis of Splenic, Portal, and Superior Mesentric vein

Timepoint

5 weeks after initiate of intervention

Method of measurement

color doppler ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: 40mg subcutaneous daily Enoxaparin for 7 days and then 100mg oral daily A.S.A tablets for 30 days after surgery

Category

Prevention

2

Description

Control Group: without administrating of drug

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan hospital

Full name of responsible person

Majid Asna Ashari

Street address

Golestan educational and therapeutic center, Farvardin street, Golestan, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Dr Behzad Sharif MakhmalZade

Street address

Esfand street, Farvardin street, Golestan, Ahvaz

City

Ahvaz

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, Ahvaz Jundishapur University of Medical Science

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**

Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Mosayeb Rafiee Pour

Position

Medical Student / Intern

Other areas of specialty/work**Street address**

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Assistant of general surgery

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Person responsible for updating data**Contact****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