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 mesentrics 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

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Name of organization / entity
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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 mesentrics 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
Ir.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

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Name of organization / entity
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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