

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of early discharge from emergency department and inpatient management of lower extremity DVT about cost and prevalence of secondary infection, gastrointestinal bleeding and pulmonary embolism.

Protocol summary

Summary

The aim of this study is comparison of early discharge from emergency department and inpatient management of lower extremity deep vein thrombosis about cost and prevalence of secondary infection, gastrointestinal bleeding and pulmonary embolism. All patients with thrombosis of the lower extremities will be enrolled in this study. Patients with a previous history of thrombosis, previous use of anticoagulants, contraindication of heparin and warfarin, hemodynamic instability and conditions unsuitable to receive treatment at home will be excluded. 120 patients will be enrolled in this study. Patients will be divided to groups. Group one will be admitted to hospital and Group two will be managed outpatient. At all patients the treatment is similar and will be enoxaparin 60 mg/kg/BD and warfarin 5 mg daily. INR will be measured first day and 3 and 5 days after beginning of treatment. When INR reached 2, the enoxaparin will be cut. The cost of treatment at 2 groups will be compared. All patients will be assessed for side effect such as infection, death and Gastrointestinal bleeding during one month.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014060517812N2**

Registration date: **2014-08-22, 1393/05/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-22, 1393/05/31

Registrant information

Name

Gholamreza Faridaalae

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of early discharge from emergency department and inpatient management of lower extremity DVT about cost and prevalence of secondary infection, gastrointestinal bleeding and pulmonary embolism.

Public title

Comparison of advantage and disadvantage of early discharge from emergency department and inpatient management of lower extremity DVT: RCT

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: all lower extremity deep vein thrombosis patients exclusion criteria: previous thrombosis; previous use of anticoagulants; contraindication of of heparin and warfarin; hemodynamic instability

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Urmia University of Medical Scinces

Street address

Urmia University of Medical Scinces; Resalat Avenue

City

Urmia

Postal code**Approval date**

2014-05-20, 1393/02/30

Ethics committee reference number

umsu.rec.1393.67

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

Lower Extermity Deep Vein Thrombosis

ICD-10 code

I 80.3

ICD-10 code description

Phlebitis and thrombophlebitis of lower extremities, unspecified

2**Description of health condition studied**

Lower Extermity Deep Vein Thrombosis

ICD-10 code

I80.1

ICD-10 code description

Phlebitis and thrombophlebitis of femoral vein

3**Description of health condition studied**

Lower Extermity Deep Vein Thrombosis

ICD-10 code

I 80.2

ICD-10 code description

Phlebitis and thrombophlebitis of other deep vessels of lower extremities

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

secundery infection

Timepoint

after 3 days, 5 days and 30 days

Method of measurement

history and physical examination

2**Description**

pulmonary emboli

Timepoint

after 3 days, 5 days and 30 days

Method of measurement

history and physical examination

Secondary outcomes**1****Description**

Gastrointestinal bleeding

Timepoint

after 3 days, 5 days and 30 days

Method of measurement

history and physical examination

2**Description**

death

Timepoint

at all time of study up to 1 month

Method of measurement

physical examination

Intervention groups

1

Description

Group control will be admitted to hospital and treatment will be administered in hospital .

Category

Other

2

Description

In intervention group, treatment will be administered out patiently.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Gholamreza Faridaalae

Street address

Emergency Ward, Imam Khomeini Hospital, Ershad Avenue

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Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical Scinces

Full name of responsible person

Iraj Mohebbi

Street address

Urmia University of Medical Scinces, Resalat Avenue

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Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Urmia University of Medical Scinces

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

Urmia University of Medical Scinces

Full name of responsible person

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Position

Assistant Professor

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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