

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Dabigatran and Enoxaparin in prophylaxy of Thromboembolic events in patient with total knee replacement surgery in Shariati hospital in 1392

Protocol summary

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Summary

This is a clinical trial on 90 patients who are candidate for TKR. Patients divided to two equal group. Venous thromboemboli (VTE) will carry out in first group by subcutaneous enoxaparin (40 mg) 12 hours before surgery and then every day up to 15 days; and in second group by dabigatran 150 mg stat and 225 mg per day up to 15 days. In this 15 days period patients will be monitored of bleeding or VTE events. Then sonodoppler of lower limbs will perform for all of them. And follow-up of bleeding will continue up to 3 months. At the end all findings will be recorded and analyzed by SPSS software.

Recruitment status

Recruitment complete

Funding source

Islamic Azad University, Najafabad branch, Isfahan Shariati Hospital

Expected recruitment start date

2013-08-12, 1392/05/21

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082513828N2**

Registration date: **2013-10-08, 1392/07/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-08, 1392/07/16

Registrant information

Name

Ahmad Mirdamadi

Name of organization / entity

Islamic Azad university, Najafabad branch

Country

Iran (Islamic Republic of)

Phone

+98 31 1223 8028

Email address

Scientific title

Comparison of Dabigatran and Enoxaparin in prophylaxy of Thromboembolic events in patient with total knee replacement surgery in Shariati hospital in 1392

Public title

Comparison of Dabigatran and Enoxaparin in prophylaxy of Thromboembolic events

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients who are candidate for total knee replacement (TKR) in shariati hospital. Age more than 18 years. Patient's consent. Exclusion criteria: History of: Bleeding disorder, Recent stroke, Major surgery, trauma, Myocardial infarction, Uncontrolled Hypertension in recent 3 months, Liver or GI disease, GI or GU bleeding in recent 6 months, Use of NSAIDs in recent week, active malignancy, Thrombocytopenia, Contrast over sensitivity, Renal failure

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Nbr121456

Secondary trial Id

556783

Registration date

2011-02-07, 1389/11/18

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2013-08-12, 1392/05/21

Ethics committee reference number

492016

Health conditions studied

1

Description of health condition studied

Thromboembolic Disease

ICD-10 code

180-189

ICD-10 code description

198

Primary outcomes

1

Description

Deep Vein Thrombophelebitis of Legs

Timepoint

15 days after surgery

Method of measurement

Sonodoppler of Legs' Veins

Secondary outcomes

1

Description

Bleeding

Timepoint

Every day up to 15 days and then up 3 months

Method of measurement

Physical Exam

Intervention groups

1

Description

Dabigatran group: Dabigatran 150 mg stat and 225 mg per day up to 15 days will be prescribed .

Category

Treatment - Drugs

2

Description

Enoxaparin group:subcutaneous enoxaparin(40 mg)12 hours before surgery and then 40 mg every day up to 15 days will be carrird out

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr. Mirdamadi

Street address

Heart Departement,Shariati Hospital,Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Şocial Security Insurance Office/ Shariati Hospital

Full name of responsible person

Dr.Mirdamadi

Street address

Heart Departement,Shariati Hospital,Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Şocial Security Insurance Office/ Shariati Hospital

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University ,Najafabad Branch

Full name of responsible person

Dr.Mirdamadi

Position

Cardiologist ,Fellowship of Echocardiography
,Assistant Professor of Medical School

Other areas of specialty/work

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Web page address

Person responsible for updating data

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Name of organization / entity

Islamic Azad University,Najafabad Branch

Full name of responsible person

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Other areas of specialty/work

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Web page address

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