

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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.

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

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

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

Soicial 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
 Soicial 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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 Heart Departement,Shariati Hospital,Isfahan
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Web page address

Person responsible for updating data

Contact

Name of organization / entity
 Islamic Azad University,Najafabad Branch
Full name of responsible person
 Dr.Mirdamadi
Position
 Cardiologist
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 Heart Departement,Shariati Hospital,Isfahan
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 n.ac.ir
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