

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A randomized comparison between dabigatran and warfarin on coagulation activity and inflammatory markers in patients with atrial fibrillation

Protocol summary

Summary

A total of 100 patients with AF who underwent catheter ablation were randomized to treatment with dabigatran (D) 110 mg twice daily or warfarin (W) adjusted to an international normalized ratio (INR) of 2.0 to 3.0 for 3 months after ablation procedure. C - reactive protein (CRP), D-dimer, prothrombin fragment F1+2 (F1+2), were measured at baseline before ablation procedures, after 30 days and after 90 days of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122311855N1**

Registration date: **2013-01-18, 1391/10/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-18, 1391/10/29

Registrant information

Name

Shahideh Amini

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-09-01, 1390/06/10

Expected recruitment end date

2013-03-15, 1391/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized comparison between dabigatran and warfarin on coagulation activity and inflammatory markers in patients with atrial fibrillation

Public title

Dabigatran versus warfarin in atrial fibrillation patients post catheter ablation

Purpose

Prevention

Inclusion/Exclusion criteria

drug-refractory, symptomatic AF who had indications for ablation included in this study. Patients were excluded in the presence of a severe heart-valve disorder, stroke within 14 days or severe stroke within 6 months before screening, a condition that increased the risk of hemorrhage, a creatinine clearance of less than 30 ml per minute, an active liver disease, and pregnancy

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tehran University of medical sciences

Street address

Tehran

City

Tehran

Postal code**Approval date**

2011-06-13, 1390/03/23

Ethics committee reference number

8933

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

Atrial Fibrillation

ICD-10 code

I48

ICD-10 code description

Atrial fibrillation and flutter

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

CRP

Timepoint

baseline, first month, third month

Method of measurement

serum samples

2**Description**

D-Dimer

Timepoint

baseline, first month, third month

Method of measurement

serum samples

3**Description**

prothrombin fragment F1+2

Timepoint

baseline, first month, third month

Method of measurement

serum samples

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

bleeding

Timepoint

baseline, first month, third month

Method of measurement

CBC test

Intervention groups**1****Description**

dabigatran (D) 110 mg twice daily (intervention group)

Category

Treatment - Drugs

2**Description**

warfarin (W) adjusted to an international normalized ratio (INR) of 2.0 to 3.0 (control group)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rajaie Cardiovascular Medical and Research Center,
Tehran University of Medical Sciences

Full name of responsible person

Bahram Fariborz Farsad

Street address

Niayesh_Valiasr Crossroads

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

shahideh amini

Street address

Tehran University of Medical Science

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

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Position

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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