

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The Study of the efficacy, safety and tolerability of low molecular weight heparin vs. unfractionated heparin in patients with embolic stroke due to atrial fibrillation

Protocol summary

Summary

Patients with Atrial fibrillation (AF) make a unique group of ischemic stroke, mostly caused by emboli from the left atrial appendage. Oral anticoagulation (Warfarin) is recommended for prevention of recurrent embolic stroke but it takes several days to reach a therapeutic international normalized ratio (INR : 2.5) so bridging therapy with a short acting intravenous anticoagulant is recommended until therapeutic INR level is reached. A common strategy is to use IV unfractionated heparin (UFH) until a standard aPTT is reached and then initiating warfarin. Another strategy is to use subcutaneous (SQ) injection of a low-molecular-weight heparin (LMWH) eg. Enoxaparin. We will compare LMWH and UFH, focusing on risk of new stroke and mortality rate. **METHOD:** This study is randomized controlled trial that will be performed in 80 patients ages between 18 and 75 with confirmed acute ischemic stroke purely due to AF who will be hospitalized in Shiraz university affiliated teaching hospitals (Faghihi and Nemazi hospitals). Patients will be randomly assigned in two groups. A brain CT will be done to confirm the absence of intracranial hemorrhage and to assess the size of cerebral ischemia. First group will receive 1 mg of enoxaparin (Clexane, Sanofi, Paris) per kilogram of body weight SQ every 12 hour with warfarin 5mg QD and both drugs will be continued until the target INR level (2.5) is reached then clexane will be discontinued. The second group will receive continuous UFH infusion 1000 unit per hour and then the dose will be adjusted to maintain a therapeutic aPTT (two times to baseline) level then warfarin will be started (5 mg QD). We will follow patients in both groups until target INR will be achieved (2.5) and after that clexane and UFH will be discontinued. Adverse events will be assessed in both groups for three months. Data will be analyzed with SPSS version 15 and Chi-square statistics. Main outcome of our study will be evaluation of new stroke, mortality, CNS

hemorrhage, major bleeding, drop out and other unwanted side effects in first week and three months after stroke

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020213698N1**

Registration date: **2014-02-02, 1392/11/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-02, 1392/11/13

Registrant information

Name

Afshin Borhani Haghighi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-01-01, 1392/10/11

Expected recruitment end date

2016-02-01, 1394/11/12

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Study of the efficacy, safety and tolerability of low molecular weight heparin vs. unfractionated heparin in patients with embolic stroke due to atrial fibrillation

Public title
The comparison of 2 types of heparin (unfractionated vs low molecular weight heparin) in patients with stroke due to atrial fibrillation

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion Criteria: confirmed diagnosis of acute ischemic stroke purely due to AF AF confirmed by ECG or 24 hour holter monitoring Patients who need initiation of anticoagulation for prevention of recurrent stroke ///
Exclusion Criteria: ages less than 18 or more than 75 no cooperation CNS hemorrhage major bleeding infarction size of more than one third of MCA territory NIHSS score more than 20 hypersensitivity to IV UFH or LMWH no informed consent other causes for stroke except AF pregnancy breast feeding uncontrolled HTN (BP more than 220/120) renal, hepatic, respiratory or cardiac failure myocardial infarction infectious endocarditis coma vasculitis dissection

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Vice chancellor for research affairs, ethics committee
Street address
Zand Avenue
City
Shiraz
Postal code
Approval date
2013-12-25, 1392/10/04
Ethics committee reference number
92-01-01-5667

Health conditions studied

1

Description of health condition studied
ischemic stroke

ICD-10 code
I63.9

ICD-10 code description

A disorder characterized by a sudden loss of sensory function due to an intracranial vascular event. A group of pathological conditions characterized by sudden, non-convulsive loss of neurological function due to brain ischemia or intracranial hemorrhages

2

Description of health condition studied
persistent atrial fibrillation

ICD-10 code
I48

ICD-10 code description

Atrial fibrillation and flutter

3

Description of health condition studied
chronic atrial fibrillation

ICD-10 code
I48.2

ICD-10 code description

Continuous or recurrent bouts of atrial fibrillation.

4

Description of health condition studied
paroxysmal atrial fibrillation

ICD-10 code
I48.0

ICD-10 code description

Sudden and episodic bouts of atrial fibrillation.

Primary outcomes

1

Description
mortality

Timepoint
7 days and 90 days after stroke

Method of measurement

close observation in hospital and telephone interview after discharge

2**Description**

ischemic stroke

Timepoint

7 days and 90 days after stroke

Method of measurement

CT scan and daily physical examination

3**Description**

hemorrhagic stroke

Timepoint

7 days and 90 days after stroke

Method of measurement

CT scan and daily physical examination

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

symptomatic CNS hemorrhage

Timepoint

7 days and 90 days after stroke

Method of measurement

CT scan

2**Description**

Non-CNS hemorrhage

Timepoint

7 days and 90 days after stroke

Method of measurement

CT scan

3**Description**

asymptomatic CNS_hemorrhage

Timepoint

7 days and 90 days after stroke

Method of measurement

CT scan

4**Description**

time to reach target INR

Timepoint

average time is 7 to 10 days (it is variable between individuals)

Method of measurement

laboratory

5**Description**

tolerability of drugs

Timepoint

during hospital admission while the patient is receiving anticoagulant

Method of measurement

daily physical exam

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

Experimental: Low molecular-weight heparin(enoxaparin ; Clexane, Sanofi, Paris) these patients will receive 1 mg of enoxaparin (clexane) per kilogram of body weight subcutaneous every 12 hour with warfarin 5mg QD and both drugs will be continued until the target INR level (2.5) is reached then clexane will be discontinued.

Category

Treatment - Drugs

2**Description**

Active Comparator: unfractionated heparin (alborz darou, Tehran) This group will receive continuous intravenous unfractionated heparin sodium infusion 1000 unit per hour initially and then the dose will be adjusted to maintain a therapeutic aPTT level (two times to baseline) then warfarin will be started (5 mg QD).

Category

Treatment - Drugs

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

Nemzi Hospital

Full name of responsible person

Farnia Feiz

Street address

Nemazi hospital, Nemazi Square, Shiraz

City

Shiraz

2**Recruitment center****Name of recruitment center**

Shahid Fghighi Hospital

Full name of responsible person

Reihaneh Sedghi

Street address

Karim Khanezand blv, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Afshin Borhani-Haghighi

Street address

Vice Chancellor for research affairs, Shiraz University of Medical Sciences, Zand Blv

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Afshin Borhani-Haghighi

Position

Neurologist, Interventional neurology fellowship

Other areas of specialty/work

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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