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)
Phone
+98 71 1612 1065
Email address
aborhani@sums.ac.ir

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 NIHS 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 comittee

Street address

Zand Aenue

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

148.2

ICD-10 code description

Continuous or recurrent bouts of atrial fibrillation.

4

Description of health condition studied

paroxysmal atrial fibtillation

ICD-10 code

148.0

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 Scienses
Full name of responsible person
Afshin Borhani-Haghighi
Street address
Vice Chancellor for research affaiars,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 Scienses
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
Street address
Zand Blv.
City
Shiraz
Postal code
Phone
+98 71 1612 1000
Fax
Email
borhanihaghighi@sums.ac.ir ,neuroab@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Afshin Borhani-Hghighi
Position
Neurologist, Interventional neurology fellowship
Other areas of specialty/work
Street address
Motahari polyclinic, Nemazee sq.
City
Shiraz
Postal code
Phone
+98 71 1612 1000
Fax
Email
borhanihaghighi@sums.ac.ir ,neuroab@gmail.com
Web page address

Person responsible for updating data

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
Street address
Motahari Polyclinic, Nemazee Sq
City
Postal code
Phone
+98 71 1612 1000
Fax
Email
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