

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Nurse-led Care on Stability Time in Therapeutic Range of INR in Ischemic Stroke Patients Receiving Warfarin

Protocol summary

Summary

The current study is designed in order to investigate the effect of nurse-led care on stability time in therapeutic range of INR (International Normalized Ratio) in ischemic stroke patients receiving Warfarin. Patients with ischemic stroke whose disease is confirmed by a neurologist doctor and referred to warfarin clinics in the specified time range of the study, and those taking warfarin for one month before starting the study were included. Patients who have to be discontinued warfarin for any reason, died during the study period due to complications from a stroke or other causes, and did not provide the necessary cooperation were excluded. In this 80 ischemic stroke patients including 40 patients in experimental group and 40 patients in the control group who referred to the nurse-based warfarin clinics affiliated to Shiraz University of Medical Sciences in 2013 were evaluated.

General information

Acronym

INR: international normalized ratio

IRCT registration information

IRCT registration number: **IRCT2016021626581N1**

Registration date: **2016-04-12, 1395/01/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-12, 1395/01/24

Registrant information

Name

Marzieh Kargar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 5016

Email address

kargar.m@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Nurse-led Care on Stability Time in Therapeutic Range of INR in Ischemic Stroke Patients Receiving Warfarin

Public title

The Effect of Nurse-led Care on Stability Time in Therapeutic Range Ischemic Stroke Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients with ischemic stroke have been one reason; Patients whose disease is confirmed by a neurologist doctor and refer to warfarin clinics in Specified time range of in the study; Patients under 76 years are allowed to enter the study; Patients who live in shiraz or around the city of Shiraz and refer to clinic in the established days; Patients who are committed to the principles of the laboratory tests are required to use the

unit for lab test checking; Patients willing to participate in the study and signed an informed consent form 7 Patients taking warfarin for one month before starting the study Exclusion criteria: Patients who have to be discontinued warfarin for any reason; Deaths during the study period due to complications from a stroke or other causes; Patients did not provide the necessary cooperation to control their INR during the study period

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not 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

Shiraz University of Medical Sciences

Street address

Research center, floor 7, Central Building University of Medical Sciences, Next to the Red Crescent, zand st

City

Shiraz

Postal code

1978 -71345

Approval date

2012-12-24, 1391/10/04

Ethics committee reference number

CT-91-6377

Health conditions studied

1

Description of health condition studied

ischaemic stroke

ICD-10 code

G 45 ,G 46

ICD-10 code description

Transient cerebral ischaemic attacks and related syndromes ,Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes

1

Description

INR

Timepoint

Baseline and then at intervals required

Method of measurement

blood test

Secondary outcomes

1

Description

Recurrent stroke and bleeding

Timepoint

At each visit of patients

Method of measurement

question and observation

Intervention groups

1

Description

control group: Lab tests for patients Adjusting the dose patients according to clinical protocols that have been developed based on the latest available protocols of thrombotic therapy Determine the therapeutic range of INR

Category

Other

2

Description

Intervention group: Lab tests for patients The necessary training related to using warfarin correctly To familiarize the patients with risk factors for recurrent stroke and bleeding and help in controlling them Adjusting the warfarin dose according to clinical protocols that have been developed based on the latest available protocols of thrombotic therapy educating the importance of treatment follow-up Determine the therapeutic range of INR

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Imam Reza (AS)
Full name of responsible person
Afshin Borhani Haghighi
Street address
Clinic of Imam Reza (AS), Namazi Square
City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Gholam Reza Hatam
Street address
Research center, floor 7, Central Building University
of Medical Sciences, Next to the Red Crescent, zand st
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
Mrs. M. kargar (Executive)
Position
Master of Nursing
Other areas of specialty/work
Street address
Nursing and midwifery School
City
Shiraz
Postal code
Phone
+98 71 3647 4254
Fax
Email
kargarm@sums.ac.ir

Web page address Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
M. kargar
Position
Master of Nursing
Other areas of specialty/work
Street address
Nursing and midwifery School
City
Shiraz
Postal code
Phone
+98 71 3647 4254
Fax
Email
kargarm@sums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mina Amiri
Position
Bachelor of nursing
Other areas of specialty/work
Street address
Nursing and midwifery School
City
Shiraz
Postal code
Phone
+98 71 3647 4254
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