

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The evaluation of the effect of Metformin on complication of ischemic strokes

Protocol summary

Study aim

The objective of this randomized, double-blind clinical trial is evaluation of the effect of Metformin on complication of ischemic strokes.

Design

In this study, 100 patients with ischemic stroke will be assigned into the study randomly and the subjects will be divided into two groups A and B randomly. Inclusion criteria of the study is Ischemic stroke patients and focal neurological symptoms. Exclusion criteria of the study is intracerebral hemorrhage (ICH); Subarachnoid hemorrhage (SAH); subdural hematoma (SDH); hypoglycemia; contraindications for metformin use; diabetic patients; venous sinus thrombosis and drug side effects.

Settings and conduct

The National Institutes of Health Stroke Scale (NIHSS) will be used to evaluate the clinical manifestations of ischemic stroke. The two groups will be followed up for 3 months. Metformin 500 mg twice in a day will be administered for seven days for group (A) and placebo will be administered for seven days for group (B). Blood glucose will be checked every 6 hours and will be recorded on the blood glucose (BS) chart. If any complications are detected, the patient will be excluded from the study. Before the intervention, the NIHSS questionnaire will be recorded then one day, three days, seven days and one month, two months, and three months after the intervention will be followed up respectively.

Participants/Inclusion and exclusion criteria

Inclusion criteria of the study is Ischemic stroke patients and focal neurological symptoms. Exclusion criteria of the study is intracerebral hemorrhage (ICH); Subarachnoid hemorrhage (SAH); subdural hematoma (SDH); hypoglycemia; contraindications for metformin use; diabetic patients; venous sinus thrombosis and drug side effects.

Intervention groups

Metformin 500 mg twice in a day will be administered for seven days for group (A) and placebo will be administered for seven days for group (B).

Main outcome variables

The National Institutes of Health Stroke Scale (NIHSS) will be used to evaluate the clinical manifestations of ischemic stroke. Before the intervention, the NIHSS questionnaire will be recorded then one day, three days, seven days and one month, two months, and three months after the intervention will be followed up respectively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160318027097N5**

Registration date: **2017-12-03, 1396/09/12**

Registration timing: **prospective**

Last update: **2017-12-03, 1396/09/12**

Update count: **0**

Registration date

2017-12-03, 1396/09/12

Registrant information

Name

Dr Faramarz Darghahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 2000

Email address

mj.naghizadeh@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical

Expected recruitment start date

2017-12-06, 1396/09/15

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of Metformin on complication of ischemic strokes

Public title

The effect of Metformin on complication of strokes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ischemic stroke patients; focal neurological symptoms.

Exclusion criteria:

intracerebral hemorrhage (ICH); subarachnoid hemorrhage (SAH); subdural hematoma (SDH); hypoglycemia; contraindications for metformin use; diabetic patients; venous sinus thrombosis; drug side effects.

Age

From **20 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization is simple, individual and using a random number table in this study. Patients who will admitted on odd days, will be assigned into group A and patients who will admitted on even days, will be assigned into group B. In this study, participants, researchers are unaware of prescription drugs.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, participants, researchers are unaware of prescription drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardebil University of Medical Sciences

Street address

Ardebil University of Medical Sciences, Daneshghah ave, Ardebil, Iran

City

Ardabil

Province

Ardabil

Postal code

5163639888

Approval date

2016-11-14, 1395/08/24

Ethics committee reference number

IR.ARUMS.REC.1395.76

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

164

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

The stroke clinical manifestations

Timepoint

Before the intervention, 24 hours, 48 hours, 168 hours, 1 month, 2 months, 3 months after the intervention

Method of measurement

National Institutes Of Health Stroke Scale

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: Tablet Metformin 500mg oral, twice in a day for 7 days

Category

Treatment - Drugs

2

Description

Control group: Placebo oral, twice in a day for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vice Chancellor for research of Ardebil University of Medical Sciences

Full name of responsible person

Dr Vahid Abbasi

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Ardebil University of Medical Sciences, Daneshgah Avenue, Ardebil, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Ardebil University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Ardebil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ardebil University of Medical Sciences

Full name of responsible person

Dr Vahid Abbasi

Position

Neurologist

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for updating data

Contact
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Full name of responsible person
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Medical student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total potential data after unidentifiable individuals

When the data will become available and for how long

Start the access period from 2019

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

Data can be used for scientific and research studies.

From where data/document is obtainable

Dr Vahid Abasi; Neurologist; V.abasi@arums.ac.ir

What processes are involved for a request to access data/document

After receiving the request email, data files will be sent in less than a week.

Comments