Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Ḍr 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

Sciences

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
Befor 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
Street address
Ardebil University of Medical Sciences, Daneshgah Avenue, Ardebil, Iran
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V.abasi@arums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Ardebil University of Medical Sciences
Full name of responsible person
Dr. Vahid Abbasi
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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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Latest degree

Specialist

Other areas of specialty/work

Neurology

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Amane Faraji

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Web page address

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