Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation the efficacy of colchicine on secondary prevention of ischemic stroke in patients with atrial fibrillation (AF)

Protocol summary

Study aim
Evaluation of the Efficacy of Colchicine on Secondary Prevention of Stroke in Patients with Atrial Fibrillation (AF)

Design
Clinical controlled trial, parallel group, double blind, 2 phase, on 100 patients, method of randomisation is block

Settings and conduct
Patients who admitted to Golestan hospital in Ahvaz city with a diagnosis of ischemic stroke for which AF is confirmed will be included in our study. Patients will be random divided into group of active and control and will be treated and followed up for a year for recurrent stroke. The Drug and placebo will be given to patients in the similar packages by an unaware person.
Participation, researchers and health care will be blinded

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients who admitted with ischemic stroke and have atrial fibrillation (AF) at the time of hospitalization. The considered age group is 18 years or older Exclusion criteria: Allergies and sensitiveness to colchicine, Patients who are taking corticosteroid, Metoteroxate. Patients with inflamatory disease, Patients with severe renal failure or hepatic failure, Patients with moderate to severe cytopenia, Contraindication receiving for rivaroxaban and Pregnant or lactating women and women in childbearing who do not take appropriate contraception

Intervention groups
All patients will be treated with rivaroxaban at the appropriate dose to prevent recurrent stroke. The active group will be additionally treated with colchicine at a dose of 0.5 mg twice daily for a year and the control group will be additionally treated with placebo twice daily for a year too.

Main outcome variables
According to reports on beneficial effects of colchicine as an anti-inflammatory drug, it may be possible to reduce the burden of disability and mortality due to recurrent stroke in high risk pateints

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130311012781N5**
Registration date: **2020-08-25, 1399/06/04**
Registration timing: **prospective**

Last update: **2020-08-25, 1399/06/04**
Update count: **0**

Registration date
2020-08-25, 1399/06/04

Registrant information

Name
Davood Kashipazha

Name of organization / entity
Ahvaz JodndiShapour University of Medical Sciencs

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-10-22, 1399/08/01

Actual recruitment start date
2020-09-21, 1399/06/31

Actual recruitment end date
2022-09-22, 1401/06/31

Trial completion date
2022-10-23, 1401/08/01

Scientific title
Evaluation the efficacy of colchicine on secondary prevention of ischemic stroke in patients with atrial fibrillation (AF)

Public title
Effect of Colchicine on secondary prevention of ischemic stroke

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who are admitted with a diagnosis of ischemic stroke and have AF at the time of hospitalization The considered age group is 18 years or older

Exclusion criteria:
Allergies and sensitivities to colchicine Patients who are taking corticosteroids, methotrexate, TNFa-blockers, interleukin1 -1b antagonist Patients with inflammatory disease such as lupus, rheumatoid arthritis, connective tissue disease or chronic infections Patients with sever Renal failure (GFR <30 ml/min/1.73 m2) or liver failure (ALT/AST > 2 above normal Patients with moderate to severe cytopenia (plt < 100000, neutrophil count < 1500) or blood dyscrasia Patients who are contraindicated for rivaroxaban Pregnant or lactating women or women in childbearing age who do not take appropriate contraception

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **20**
Actual sample size reached: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of randomization is bolck in this study. The randomized codes will be produced for 100 patients and then patients will be specified in active and control gruop according to randomization list.

Blinding (investigator's opinion)
Double blinded

Blinding description
participants, principle investigator ، healthcare providers , data collectors ,outcome assessors، data safty and monitoring board and manuscript writers are all blinded in our study. Patients will be divided into group A and B by a person who is unaware of the patients clinical information by the randomization list. The patients will be treated and followed up according to produced protocol for a year

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of ahvaz university of medical sciences

Street address
Esfand Ave., golestan Blvd., Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135733118

Approval date
2020-02-24, 1398/12/05

Ethics committee reference number
IR.AJUMS.REC.1398.927

Health conditions studied

1

Description of health condition studied
Ischemic stroke.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Recurrence of stroke

Timepoint
3, 6, 9 and 12 months after the beginning of study

Method of measurement
Clinical history and imaging finding

Secondary outcomes

empty

Intervention groups

1

Description
All patients will be treated wih the rivaroxaban at the appropriate of dose once daily for a year. Patients will be additionally treated with colchicine at the dose of 0.5 mg twice daily for a year in intervention group. The colchicine tablet will be produced from mofid pharmacy company. Patients will be followed up every three months for a year.

Category
Treatment - Drugs

2

Description
All patients will be treated wih the rivaroxaban at the appropriate of dose once daily for a year. Patients will be additionally treated with placebo twice daily for a year in control group. The placebo tablet will be produced from mofid pharmacy company. Patients will be followed up every three months for a year.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of neurology of golestan hospital

Full name of responsible person
Davood kashipazha

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Farvardin Ave., Golestan Blvd., Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mohammad badavi

Street address
Esfand Ave., Golestan Blvd., Ahvaz

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itc@ajums.ac.ir

Web page address
http://vchresearch.ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Department Research and technology, Ahvaz jundishapur 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
Ahvaz University of Medical Sciences

Full name of responsible person
Davood kashipazha

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Neurology

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Person responsible for scientific inquiries

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Specialist
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Person responsible for updating data

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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The primary clinical outcome of participants will be shared by the analysis of collected data.
When the data will become available and for how long
6 months after publication of results
To whom data/document is available
available for people who working in academic institutions
Under which criteria data/document could be used
Primary clinical outcome of participants will be shared by tables and charts.
From where data/document is obtainable
Davood kashipazha _ Department of Neurology of Golestan Hospital in Ahvaz. Email: dakashi47@gmail.com
What processes are involved for a request to access data/document
Please your request will be send by email. our response will be send you by email during a month.
Comments