Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of doxycycline versus placebo on clinical outcomes in patients with ischemic stroke: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of doxycycline versus placebo on clinical outcomes in patients with ischemic stroke

Design
This is a double-blind randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Besat Hospital in Hamadan city on 70 eligible patients. The patients with ischemic stroke will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double -blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 85 years Ischemic stroke in the last 24 hours Exclusion criteria: Pregnancy and lactation History of ischemic stroke

Intervention groups
Intervention group: Routine treatment plus doxycycline capsule 100 mg every 12 hours for 7 days Control group: Routine treatment plus placebo starch) capsule every 12 hours for 7 days

Main outcome variables
Primary outcome: Neurological dysfunction, functional dysfunction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N432**
Registration date: **2022-06-28, 1401/04/07**
Registration timing: **prospective**

Last update: **2022-06-28, 1401/04/07**
Update count: **0**

Registration date
2022-06-28, 1401/04/07

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-06, 1401/05/15

Expected recruitment end date
2023-08-06, 1402/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of doxycycline versus placebo on clinical outcomes in patients with ischemic stroke: a double-blind randomized clinical trial

Public title
Effect of doxycycline versus placebo on clinical outcomes in patients with ischemic stroke

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 85 years Ischemic stroke in the last 24 hours
Exclusion criteria:
Pregnancy or lactation History of ischemic stroke

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2022-06-25, 1401/04/04

Ethics committee reference number
IR.UMSHA.REC.1401.317

Health conditions studied

1

Description of health condition studied
Ischemic stroke

ICD-10 code
I63

ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
Neurological dysfunction

Timepoint
Before intervention, one week, one and three months later

Method of measurement
Using the NIH Stroke Scale (NIHSS)

2

Description
Functional dysfunction

Timepoint
Before intervention, one week, one and three months later

Method of measurement
Using the modified Rankin Scale (mRS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine treatment plus doxycycline capsule 100 mg every 12 hours for 7 days

Category
Treatment - Drugs

2

Description
Control group: Routine treatment plus placebo starch) capsule every 12 hours for 7 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital in Hamadan city

Full name of responsible person
Zahra Aminian

Street address
Besat Hospital, Shahed Square

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3364 0030

Email
zahra.amn95@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Reza Shokoohi

Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0717

Email
info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Zahra Aminian

Position
Medical Student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
00989182055594

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0572

Email
zahra.amn95@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Mojtaba Khazaei

Position
Neurologist

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

Street address
School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0572

Email
khazaeimojtaba@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Jalal Poorolajal
Position
Professor of Epidemiology
Latest degree
Medical doctor
Other areas of specialty/work
Epidemiology
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available