

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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)

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+98 81 1838 0090

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##### 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**

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**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

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Shokoohi

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr. Mojtaba Khazaei

**Position**

Neurologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

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## 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

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**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