Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the effect of Doxycycline on biomarkers of oxidative stress in patients with ischemic stroke: a randomized clinical trial study

Protocol summary

Study aim
Determining the effect of doxycycline on oxidative stress biomarkers in ischemic stroke patients: a clinical trial study.

Design
A controlled, parallel-group, double-blind, randomized, phase 1 clinical trial on 24 patients. The rand function of Excel software will be used for randomization.

Settings and conduct
Hamedan Ba'ath Hospital, ischemic stroke patients and the control group are blood sampled one day before starting treatment with doxycycline and 7 days after treatment with doxycycline. will be done. The study will be double-blinded by nurses and patients. The rand function of Excel software will be used for randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Not using any combination with antioxidant effects in the last month Exclusion criteria: Drug intolerance and side effects

Intervention groups
In the intervention group, patients will receive 100 mg doxycycline every 12 hours for 7 days in addition to standard treatments. T

Main outcome variables
The level of MDA in the serum of ischemic stroke patients before and after treatment with doxycycline in the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170114031921N6**
Registration date: **2024-02-24, 1402/12/05**
Registration timing: **prospective**

Last update: **2024-02-24, 1402/12/05**
Update count: **0**

Registration date
2024-02-24, 1402/12/05

Registrant information

Name
homa naderifar

Name of organization / entity
Tehran

Country
Iran (Islamic Republic of)

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homa.naderifar@ut.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-29, 1402/12/10

Expected recruitment end date
2025-02-17, 1403/11/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of Doxycycline on biomarkers of oxidative stress in patients with ischemic stroke: a randomized clinical trial study

Public title
Evaluating the effect of Doxycycline on biomarkers of oxidative stress in patients with ischemic stroke: a randomized clinical trial study

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical diagnosis of acute hemispheric ischemic stroke Focal neurological disorder MRI and CT radiological findings consistent with the clinical diagnosis of acute hemispheric stroke Absence of other concurrent inflammatory disease

Exclusion criteria:

Available evidence based on acute or chronic intracerebral hemorrhage and cerebral aneurysm Drug intolerance and side effects

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of patients into two control and intervention groups will be done in a random block. So that there will be 2 sheets A and two sheets B in one envelope, and each time by removing one of the sheets, the patient will be placed in the control or intervention group. The removed sheet will not be returned to the envelope until the sheets inside the envelope are exhausted. Randomization of patients in study groups will be done by a nurse who is not part of the research team

Blinding (investigator's opinion)

Double blinded

Blinding description

Allocation of patients into two control and intervention groups will be done in a random block. So that there will be 2 sheets A and two sheets B in one envelope, and each time by removing one of the sheets, the patient will be placed in the control or intervention group. The removed sheet will not be returned to the envelope until the sheets inside the envelope are exhausted. Randomization of patients in study groups will be done by a nurse who is not part of the research team

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Hamadan University of Medical Scieneces

Street address

No. 2, Shahid Fahmideh Blvd., Ghaem Ave., Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2022-12-24, 1401/10/03

Ethics committee reference number

IR.UMSHA.REC.1401.840

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

Z82.3

ICD-10 code description

Family history of stroke

Primary outcomes

1

Description

Malone dialdehyde

Timepoint

One day before starting doxycycline treatment and 7 days after treatment

Method of measurement

It is checked by using ELISA Reed kits and reading the wavelength by variable spectrophotometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 100 mg doxycycline every 12 hours for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Basath Hospital

Full name of responsible person
Mojtaba Khazai

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Reza Shokohi

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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
Hamedan University of Medical Sciences

Proportion provided by this source
10

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
fereshteh mehri

Position
assassinate

Latest degree
Ph.D.

Other areas of specialty/work
Toxicology

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Person responsible for updating data

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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
No - There is not 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