Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

The effect of defroxamine on neurological and radiological outcome after spontaneous intracerebral hemorrhage

Protocol summary

Study aim
The effect of defroxamine on neurological and radiological outcome after spontaneous intracerebral hemorrhage

Design
This study will be performed as a randomized clinical trial (4 blocks), one-sided blind, with control group, with parallel groups and as a phase 2-3 with the participation of 42 patients with spontaneous cerebral hemorrhage.

Settings and conduct
This study will be performed with the participation of 42 patients with spontaneous cerebral hemorrhage admitted to Shohada Hospital (Tabriz University of Medical Sciences). Patients will be given two drugs, deferoxamine (intervention group - for three consecutive days) and placebo (control group, for three consecutive days) during hospitalization. The data analyzer will be unaware of the grouping of patients and will be blind during the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria include stroke, spontaneous cerebral hemorrhage, and consent to participate in the study, and exclusion criteria include brain surgery, stroke over the past six months, and deferoxamine sensitivity.

Intervention groups
In this study, a randomized, single-blind clinical trial will be performed in Shohada Hospital (Tabriz University of Medical Sciences). Turn) and control (placebo administration for three consecutive days and once a day) will be divided and after the intervention, their level of consciousness will be compared.

Main outcome variables
Level of consciousness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N30**
Registration date: **2022-05-13, 1401/02/23**
Registration timing: **prospective**

Last update: **2022-05-13, 1401/02/23**
Update count: **0**

Registration date
2022-05-13, 1401/02/23

Registrant information

Name
Mehdi Khanbabayi Gol

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3334 7054

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khanbabayimehdi69@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-31, 1401/03/10

Expected recruitment end date
2022-10-02, 1401/07/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of defroxamine on neurological and radiological outcome after spontaneous intracerebral hemorrhage

Public title

Deferoxamine on neurological and radiological implications for cerebral hemorrhage

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Brain stroke Spontaneous cerebral hemorrhage Satisfaction to participate in the study

Exclusion criteria:

Requires brain surgery Stroke over the last six months Hypersensitivity to deferoxamine

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block random division method (4 blocks) is used. One of the study partners, for whom no blinding was performed, named the method of treatment of defroxamine with the letter A and the method of treatment of placebo with the letter B. The researcher then distributes packages A and B among the patients referred to participate in the study by block random division method (4). Then, from the created blocks, enough blocks are randomly selected to reach the required sample size. To make a random sequence, we give possible blocks (11 blocks) from one to 11 numbers. Depending on the sample size, any number of 4 blocks that are needed will be used. Select the number of blocks from the table of random numbers and based on these numbers, the sequence of blocks in each group will be determined.Finally, random allocation will be done with the help of 11 quadruple blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical consultant of this project will be unaware of the type of grouping of participants; The final results will be delivered to the statistical consultant. As the statistical consultant will not be in the process of grouping the participants; Therefore, he is blind during the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2022-05-11, 1401/02/21

Ethics committee reference number

IR.TBZMED.REC.1401.142

Health conditions studied

1

Description of health condition studied

level of consciousness

ICD-10 code

R40.244

ICD-10 code description

Other coma, without documented Glasgow coma scale score, or with partial score reported

Primary outcomes

1

Description

Level of consciousness

Timepoint

Before the intervention, one week and one month after the end of the intervention

Method of measurement

With the help of GCS criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Twenty-one patients with a diagnosis of spontaneous bleeding after random allocation will be included in this study. After being admitted to the relevant ward, deferoxamine (manufactured by Obaidi Company) will be injected for three consecutive days (once a day). Consciousness status will be measured before the intervention, one week and one month after the intervention using the GCS instrument.

Category
Treatment - Drugs

2

Description
Control group: Twenty-one patients with a diagnosis of spontaneous bleeding after random allocation will be included in this study. After being admitted to the relevant ward, placebo (manufactured by Obaidi Company) will be injected for three consecutive days (once a day). Consciousness status will be measured before the intervention, one week and one month after the intervention using the GCS instrument.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada Hospital

Full name of responsible person
Mohammad Shimia

Street address
Shohada Hospital, Golshahr Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Mohammad Shimia

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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Position
Neurosurgery assistant

Latest degree
Medical doctor

Other areas of specialty/work
Neurosurgery

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

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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