

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 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

Email address

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 deferoxamine 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 centers1**Recruitment center****Name of recruitment center**

Shohada Hospital

Full name of responsible person

Mohammad Shimia

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Shohada Hospital, Golshahr Ave

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Sponsors / Funding sources1**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**

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Full name of responsible person

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Neurosurgery assistant

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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

Nursery

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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