

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effectiveness of Tizanidine in improving spasticity in patients with diffuse axonal injury related to brain injury: a randomized double-blind trial

Protocol summary

Study aim

Effectiveness of tizanidine drug in improving spasticity in patients with diffuse axonal injury related to brain injury

Design

Patients in the intervention group will use tizanidine 4 mg tablets twice a day, and the control group will use placebo tablets twice a day, which have the same shape and appearance as tizanidine tablets. None of the patients will receive drugs that have muscle relaxant effects, such as baclofen or methocarbamol, during the study. The amount of muscle spasm using the modified Ashworth scale at the time of admission and discharge from the hospital, and the final outcome of the patients (discharge or death) will also be calculated and recorded for each patient.

Settings and conduct

Shahid Dr. Rahnamon Hospital in Yazd

Participants/Inclusion and exclusion criteria

Patients aged 15 to 60 years and diagnosed with diffuse axonal damage based on the diagnosis of a neurosurgery specialist and imaging evidence, who do not have chronic liver and kidney disease and have the ability to receive medication orally or through a nasogastric tube. Conditions of non-entry: lack of informed consent by the patient's first-degree relatives, spinal cord injury, penetrating head injury, previous traumatic brain injury, kidney failure, pregnancy, history of allergy to tizanidine, and patients whose treatment plan changes during the study, for example, the need for surgery to find, is

Intervention groups

The intervention group received tizanidine tablets and the control group received placebo tablets

Main outcome variables

The primary outcome measured includes The Modified Ashworth Scale (MAS), which is evaluated in this measure of changes in muscle tone. The secondary outcome measured is The Disability Rating Scale (DRS)

score. In this measure, key aspects of disability are assessed, including the ability to open the eyes, the ability to communicate, and motor response.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190810044500N27**

Registration date: **2024-10-03, 1403/07/12**

Registration timing: **prospective**

Last update: **2024-10-03, 1403/07/12**

Update count: **0**

Registration date

2024-10-03, 1403/07/12

Registrant information

Name

Fatemeh Saghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of Tizanidine in improving spasticity in patients with diffuse axonal injury related to brain injury: a randomized double-blind trial

Public title

The effect of tizanidine on spasticity in patients with diffuse axonal injury

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 15 to 60 years Patients diagnosed with diffuse axonal damage based on neurosurgery expert diagnosis and imaging evidence have the ability to receive medication orally or through a nasogastric tube. Do not have chronic liver and kidney disease

Exclusion criteria:

The presence of chronic kidney and liver diseases Lack of informed consent by the patient's first degree relatives spinal cord injury , Penetrating head injury , Previous traumatic brain injury Kidney and liver failure pregnancy History of allergy to tizanidine Patients who change their treatment plan while studying, for example, need surgery.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the table of random numbers and using the Random allocation software version 1.0 under Windows, we generate a random sequence using a simple random allocation method. In this table, we specify from 1 to 64 and each number is assigned to an intervention group (A or B) is assigned

Blinding (investigator's opinion)

Double blinded

Blinding description

Study participants and the research team remain unaware of which patient has used which type of medication.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Faculty of Ethics of Medical Sciences - Shahid Sadoughi University of Medical Sciences

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Postal code

8915173143

Approval date

2024-07-06, 1403/04/16

Ethics committee reference number

IR.SSU.MEDICINE.REC.1403.058

Health conditions studied**1****Description of health condition studied**

Spasticity in patients with diffuse axonal injury

ICD-10 code

G52.7

ICD-10 code description

Disorders of multiple cranial nerves

Primary outcomes**1****Description**

The Modified Ashworth Scale (MAS)

Timepoint

Days 1, 3, 6, 9, 12 and 15 after head trauma

Method of measurement

Check muscle tone

Secondary outcomes**1****Description**

The Disability Rating Scale

Timepoint

0, 1, 3 and 7 days and discharge day

Method of measurement

DRS rates eight subscales; In fact, it measures the level of consciousness, cognitive independence in self-care, employability and the need for supervision and subscale ratings, and finally gives a total score to their sum. These categories are: no disability (score 0), mild (1), partial (2-3), moderate (4-6), moderately severe (7-11), severe (12-16), very severe (17-21), vegetative state (22-24), and severe vegetative state (25-29) and death (30). DRS is scored by a neurosurgeon.

Intervention groups

1

Description

Intervention group: Patients in the intervention group will use tizanidine 4 mg tablets twice a day (Ector company) during their stay in the intensive care unit.

Category

Treatment - Drugs

2

Description

Control group: Patients in the intervention group will use a placebo pill that has the same shape and appearance as tizanidine twice a day during their stay in the intensive care unit.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dr. Rahnemoon hospital Yazd

Full name of responsible person

Sepideh Sadat Mirbagheri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Yazd University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Saghafi

Position

استادیار

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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