Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Saghafi

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
Street address
Shahid Sadoughi University of Medical Sciences,Shohaday gomnam Blvd,Yazd
City
yazd
Province
Yazd
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
Yazd 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
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