

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of Betaxolol in improving the Glasgow Outcome Scale Extended (GOSE) of the acute phase of patients with mild to moderate Traumatic Brain Injury: A double blinded randomized Clinical Trial

Protocol summary

Study aim

Evaluation of Betaxolol in improving the Glasgow Outcome Scale Extended (GOSE) of the acute phase of patients with mild to moderate Traumatic Brain Injury

Design

This study is a randomized, double-blind clinical trial using a stratified block randomization method with a block size of 4 with parallel groups, and it involves 104 individuals who have suffered mild to moderate traumatic brain injury. The intervention group receives medication, and the control group receives a placebo.

Settings and conduct

This study is conducted on patients with traumatic brain injuries admitted to Shahid Sadegh Ganji Hospital in Borazjan. It is a double-blind clinical trial, in which neither the researcher nor the patients know whether the substance used is the actual drug or a placebo.

Participants/Inclusion and exclusion criteria

The participants are patients aged 18 to 65 with mild to moderate traumatic brain injury (GCS score of 9 or higher). Exclusion criteria for the study include patients with penetrating head trauma, unknown time of injury, patients with spinal cord injuries, patients with cardiovascular diseases, unstable hemodynamics, and patients who are candidates for craniotomy.

Intervention groups

Intervention group takes Betaxolol Hydrochloride 5mg once orally. Control group takes placebo once orally.

Main outcome variables

Glasgow Outcome Scale Extended (GOSE)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240415061488N1**

Registration date: **2024-04-25, 1403/02/06**

Registration timing: **prospective**

Last update: **2024-04-25, 1403/02/06**

Update count: **0**

Registration date

2024-04-25, 1403/02/06

Registrant information

Name

Homayoun Zeynodini Meimand

Name of organization / entity

Country

Iran (Islamic Republic of)

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homayoon731@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-21, 1403/03/01

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Betaxolol in improving the Glasgow Outcome Scale Extended (GOSE) of the acute phase of patients with mild to moderate Traumatic Brain Injury: A double blinded randomized Clinical Trial

Public title
Evaluation of Betaxolol in improving the acute phase of patients with mild to moderate Traumatic Brain Injury

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with mild to moderate traumatic brain injury (GCS score of 9 or above) Age 18 to 65 years old
Exclusion criteria:
Patients with penetrating head trauma Unspecified time of trauma Patients with spinal cord injury Patients with cardiovascular diseases Hemodynamic instability Candidates for craniotomy

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned to two groups, intervention (A) and control (B), using a stratified block randomization method with block size of four. The classification and randomization are carried out by a research assistant who has no involvement in selecting patients or evaluating patient outcomes. Given the four-member block size, there are six possible configurations for patient allocation, such that two individuals are placed into the intervention group and two into the control group (for example, ABBA and BBAA). Patients are categorized by age into two groups: those under 40 years and those 40 years and older, with members of each age group divided into blocks of four. A random one of the six possible configurations is then selected for each block, placing patients in the designated groups accordingly. This process will continue until sample collection is complete.

Blinding (investigator's opinion)
Double blinded

Blinding description
The same individual who carried out the randomization of patient selection also gives the drug or placebo of each patient to the researcher. Since the drug and placebo are identical in appearance, the researcher will not be able to distinguish between the two. The patient is also unaware of which one they are receiving.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Sciences
Street address
South Sheikh Bahayi Ave., Mollasadra Ave., Vanak Sq.
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2024-03-16, 1402/12/26
Ethics committee reference number
IR.BMSU.BAQ.REC.1403.019

Health conditions studied

1

Description of health condition studied
Traumatic Brain Injury
ICD-10 code
S06
ICD-10 code description
Intracranial injury

Primary outcomes

1

Description
Score of Glasgow Outcome Scale Extended (GOSE)
Timepoint
Day 1 and 14 after taking medication
Method of measurement
Glasgow Outcome Scale Extended (GOSE) Questionnaire

Secondary outcomes

1

Description
Score of The Working Memory Questionnaire
Timepoint
Day 1 and 14 after taking medication
Method of measurement
The Working Memory Questionnaire

2

Description

Score of Visual analogue scale (VAS)

Timepoint

Day 1 and 14 after taking medication

Method of measurement

Visual analogue scale (VAS)

3

Description

Score of Mini Mental State Examination (MMSE)

Timepoint

Day 1 and 14 after taking medication

Method of measurement

Score of Mini Mental State Examination (MMSE)

4

Description

Presence of drug side effects

Timepoint

Day 1 and 14 after taking medication

Method of measurement

If the patient confirms any side effects of the drug "Yes"
otherwise "No"

Intervention groups

1

Description

Intervention group: Taking Betaxolol Hydrochloride 5mg, Oral, Single Dose, This drug is given to the patients of the intervention group one time after admission to the hospital.

Category

Treatment - Drugs

2

Description

Control group: Taking placebo, Oral, Placebo is given to the patients of the control group one time after admission to the hospital.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadegh Ganji Hospital, Borazjan (Bushehr University of Medical Sciences)

Full name of responsible person

Mahammad Eslamian

Street address

Sadegh Ganji Hospital, Emam Reza Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mousareza Anbarlouei

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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

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

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Yes

Title of funding source
Boushehr University of Medical Sciences

Proportion provided by this source
50

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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Mousareza Anbarlouei

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Neurosurgery

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work
Neurosurgery

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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

