Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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Iran (Islamic Republic of)
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Email address
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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.
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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
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Sponsors / Funding sources

1

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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
Boushehr University of Medical Sciences
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Email
md.eslamian@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
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
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Assistant Professor
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Person responsible for scientific inquiries

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Person responsible for updating data

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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