Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of the effect of glibenclamide on improving the treatment results and consciousness of patients with traumatic brain diffuse axonal injury

Protocol summary

Study aim
we examined the effect of this drug on three months GOS after TBI.

Design
Clinical trial, prospective, with two groups of case and control, double-blind, randomized, on 96 patients. Excel random function was used for randomization.

Settings and conduct
The drug or placebo was injected by the nurse. GCS was measured at discharge. Patients were referred to Ahvaz Golestan Hospital as outpatients after three months and GOS was measured after three months. The study was performed blindly.

Participants/Inclusion and exclusion criteria
All TBI patients with moderate(9-12)to severe(4-8) GCS referred to the emergency department of Golestan Hospital in Ahvaz with a maximum of 24 hours after TBI were included in study. Patients with a history of other diseases and those who needed other therapeutic and pharmacological interventions were excluded from the study.

Intervention groups
Patients were randomly divided into one of two case group receiving 10 mg of glibenclamide daily for 10 days or the control group receiving placebo with the same dose for 10 days.

Main outcome variables
GCS, GOS, length of stay in ICU, mortality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200815048418N1**
Registration date: **2020-12-12, 1399/09/22**
Registration timing: **retrospective**
Last update: **2020-12-12, 1399/09/22**
Update count: **0**

Registration date
2020-12-12, 1399/09/22

Registrant information

Name
hesam rasoulian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-18, 1397/11/29

Expected recruitment end date
2019-06-21, 1398/03/31

Actual recruitment start date
2019-03-06, 1397/12/15

Actual recruitment end date
2019-06-21, 1398/03/31

Trial completion date
2019-06-21, 1398/03/31

Scientific title
Evaluation of the effect of glibenclamide on improving the treatment results and consciousness of patients with traumatic brain diffuse axonal injury

Public title
Evaluation of the effect of glibenclamide in patients with traumatic diffuse brain injuries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All TBI patients with moderate(9-12)to severe(4-8) GCS referred to the emergency department of Golestan Hospital in Ahvaz with a maximum of 24 hours after TBI.

Exclusion criteria:

Patients with diabetes mellitus, patients that required surgery, spinal cord injury, patients with any known history of renal or hepatic diseases, patients with past medical history of brain tumors, blood glucose <50 g/dL or >500 mg/dL on admission; internal organs diseases, penetrating brain injury, creatinine >2.5mg/dL or on hemodialysis, total bilirubin >1.5 times of normal value, infections, or previous craniotomy; pregnant patients or patients who intended to breastfeed after being discharged; patients with international normalized ratio >1.5 or use of antiplatelets or anti coagulants within 7 days before admission, history of glucose-6-phosphate dehydrogenase deficiency or any diagnosed allergy to sulfonylurea; patients with contusions in brainstem or an systolic blood pressure <90 mm Hg without response to fluid resuscitation; and patients with contraindications to oral route for taking the medication or treatment with other investigational agents during hospitalization.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **96**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In this method, all patients during the study period will be equally and randomly divided into case and control groups and will enter the study. Randomization of study samples will be done in two groups by random allocation. For this purpose, we first determine the total sample size, then randomly assign a set of them to group A and the rest to group B. we do this using a table of random numbers. In assigning patients to two hidden groups Random sequencing will be considered throughout the process and the patient and researcher will not be aware of the group the patient is entering. Awareness of subsequent allocation may lead to the elimination of specific patients by the researcher based on their disease prognosis, or patients with better conditions enter the intervention group and patients with worse conditions enter the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants were kept blind to being in the intervention group or control group. Patients were assured that their information would be kept strictly confidential. Patients were given full explanations about the objectives, method of implementation of the plan and its possible side effects, and if they or their legal guardians were willing, consent was obtained and included in the study. They were blind from being in any of intervention or control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur university of medical sciences

Street address

Esfand Ave, Farvardin Blvd, Ahvaz

City

ahvaz

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Khouzestan

Postal code

15794-61357

Approval date

2019-02-16, 1397/11/27

Ethics committee reference number

IR.AJUMS.REC.1397.854

Health conditions studied

1

Description of health condition studied

traumatic brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

Glasgow outcome scale

Timepoint

Three months after TBI

Method of measurement

Glasgow outcome scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: daily 10 mg glibenclamide for 10 days.
Category
Treatment - Drugs

2

Description
Control group: placebo Prescription
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Hesam Rasoulian
Street address
Golestan hospital, Farvardin Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Ahmadi Moghadam
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Hesam Rasoulian
Position
Student
Latest degree
A Level or less
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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