Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

A clinical trial of effects of oral glibenclamide on size of brain contusions and their peripheral edema in patients with moderate and severe traumatic brain injury

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of oral glibenclamide on size of brain contusions and their peripheral edema in patients with moderate and severe traumatic brain injury

Design

Study design: Randomized double-blind placebo-controlled clinical trial.Patients will be randomly assigned to 2 study groups with a 1-to-1 ratio using a computerized random digit generator utilizing the admission number of the patients. Randomization will be done by the use of computer software

Settings and conduct

Among patinets referred to Shahid Beheshti Hospital affiliated to Kashan University of Medical Sciences, 70 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged between 18 and 75 years with documented closed head injury, non-penetrating brain injury, having brain contusions on initial brain CT scan, GCS: 5-13 without influence of sedations upon admission. Exclusion criteria: Patients with spinal cord injury or spinal column instability with neurologic deficit, patients with INR>1.6, systolic BP less than 90 mmHg on admission without respond to fluid resuscitation, Pregnant women or a positive pregnancy test or those who intend to breastfeed during study days.

Intervention groups

Intervention group: Oral glibenclamide 15 mg (three tablet, 5 mg each, chemidarou Pharmaceutical Company), daily for 10 days. Control group: Placebo agent (Barij Essence Pharmaceutical Company, 3 tablets Daily, for 10 days

Main outcome variables

Primary outcome: Brain contusion volume determined by CT-volumetry. Secondary outcome: precontusional edema volume and Glasgow Outcome Scale (GOS).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N45**
Registration date: **2019-01-21, 1397/11/01**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-21, 1397/11/01**
Update count: **0**

Registration date

2019-01-21, 1397/11/01

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A clinical trial of effects of oral glibenclamide on size of brain contusions and their peripheral edema in patients with moderate and severe traumatic brain injury

Public title
The effects of oral glibenclamide in patients with traumatic brain injury
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: Patients aged between 18 and 75 years with documented closed head injury patients with non-penetrating brain injury Having brain contusions on initial brain CT scan GCS: 5-13 without influence of sedations upon admission Random blood sugar more than 70 mg/dl before the intervention Patients without a lesion on brain CT which urges a surgical evacuation at any time of hospital admission (Surgical EDH, SDH, ICH or midline shift>5mm and decompressive craniectomy) Patients without severe renal disorder from past history or Cr>2.5 Patients without severe liver disease from past history or total bilirubin above 1.5 times of normal value.
Exclusion criteria:
Exclusion criteria: Patients with spinal cord injury or spinal column instability with neurologic deficit. Patients with INR>1.6 Systolic BP less than 90 mmHg on admission without respond to fluid resuscitation. Pregnant women or a positive pregnancy test or those who intend to breastfeed during study days Usage of warfarin, heparin, clopidogrel, LMWH within 72 hours prior to traumatic event Usage of glibenclamide 72 hours prior to traumatic event Patients with PaO2<60 mmHg Patients with diabetes mellitus on either oral hypoglycemic agents or insulin before TBI
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to 2 study groups with a 1-to-1 ratio using a computerized random digit generator utilizing the admission number of the patients. Randomization will be done by the use of computer software.
Blinding (investigator's opinion)
Double blinded
Blinding description
Allocation concealment will be done by having procedure indicator cards inside a set of numbered opaque sealed envelopes. Patients will be allocated to treatment groups, after screening. None of the staff or patients will have access to the randomization codes during the study. Participants, investigators or the assessors of the outcomes are unaware of the study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Approval date
2018-11-05, 1397/08/14
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1397.066

Health conditions studied

1

Description of health condition studied
Brain contusion
ICD-10 code
S06.3
ICD-10 code description
Focal traumatic brain injury

Primary outcomes

1

Description
Brain contusion volume
Timepoint
On admission, day 3 and 7 days after intervention
Method of measurement
CT-volumetry of brain contusions

Secondary outcomes

1

Description
precontusional edema volume
Timepoint
On admission, day 3 and 7 days after intervention
Method of measurement
CT-volumetry of brain contusions

2

Description
Glasgow Outcome Scale (GOS)
Timepoint
On Discharge time and 3 months later
Method of measurement
Physical Examination

Intervention groups

1

Description
Intervention group: Oral glibenclamide 15 mg (three tablet, 5 mg each, chemidarou Pharmaceutical Company), daily for 10 days
Category
Treatment - Drugs

2

Description
Control group: Placebo agent (Barij Essence Pharmaceutical Company, 3 tablets Daily, for 10 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr. Esmaeil Fakharian
Street address
Ghotbe Ravandi Boulevard, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan 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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Dr. Sajad Yazdani
Position
Resident of Neurosurgery
Latest degree
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Other areas of specialty/work
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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