

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 patients 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

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Name of organization / entity

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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

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Province

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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. Esmail Fakharian

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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

Medical doctor

Other areas of specialty/work

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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