

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of oral glibenclamide on reduction of size of brain contusions and peri contusional edema and prognosis of patients with moderate and severe traumatic brain injury: a randomized clinical trial

Protocol summary

Summary

The aim of the current study is to determine effects of oral Glibenclamide in moderate and severe TBI and its role in reduction of size of contusions and pericontusional edema. For this purpose we will include 104 patients with moderate and severe traumatic brain injury (TBI) between 18 to 75 years within 10-hours of injury. Those undergoing surgical evacuation of the hematoma, spinal cord injury and coagulopathy would be excluded from the study. The patients would be assigned to two study groups to receive oral glibenclamide in a dosage of 10mg daily for 10 days or placebo. The Glasgow Outcome Scale (GOS) and GOSE and Disability Rating scale (DRS) would be assessed after 1, 3 and 6 months of injury. The brain contusion volume and edema would be measured on admission, 3rd day and 10th day after the intervention. Clinical scales and size of contusions and pericontusional edema will be compared in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121720353N1**
Registration date: **2015-05-15, 1394/02/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-15, 1394/02/25

Registrant information

Name

Nima Derakhshan

Name of organization / entity

Neurosurgery Department, Shiraz University of

Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Shiraz University of Medical Sciences

Expected recruitment start date

2015-04-01, 1394/01/12

Expected recruitment end date

2016-10-01, 1395/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of oral glibenclamide on reduction of size of brain contusions and peri contusional edema and prognosis of patients with moderate and severe traumatic brain injury: a randomized clinical trial

Public title

Effects of oral glibenclamide in patients with traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Documented closed head injury; Age between 18 and 75 years; Having brain contusions on initial brain CT scan; Taking the first dosage of

medication within first 10 hours of trauma event;
GCS:5-13 without influence of sedations upon admission;
Obtaining written informed consent from legally authorized representative
Exclusion criteria: Having 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); Spinal cord injury or spinal column instability with neurologic deficit; Penetrating brain injury; Any blood glucose under 50mg/dL or over 500mg/d; Severe renal disorder from past history or Cr>2.5 or patients on hemodialysis; Severe liver disease from past history or total bilirubin above 1.5 times of normal value; INR>1.6; Systolic BP below 90mmHg on admission without respond to fluid resuscitation; Pregnant women or a positive pregnancy test or those who intend to breastfeed during study days; Associated severe non-survivable injury; History of previous brain problems (Tumor, infections, strokes, ...); Usage of warfarin, heparin, clopidogrel, LMWH within 72 hours prior to traumatic event

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

Zand Avenue

City

Shiraz

Postal code**Approval date**

2015-01-25, 1393/11/05

Ethics committee reference number

93-0101-7757

Health conditions studied**1****Description of health condition studied**

Brain contusion

ICD-10 code

S06.3

ICD-10 code description

Focal brain injury

Primary outcomes**1****Description**

Brain contusion and precontusional edema volume

Timepoint

Onadmission, day 3 and 10 after intervention

Method of measurement

CT-volumetry of brain contusions

2**Description**

Outcome

Timepoint

6 months after intervention

Method of measurement

Glasgow Outcome Scale (GOS)

Secondary outcomes

empty

Intervention groups**1****Description**

Group 1: Oral glibenclamide 10 mg daily for 10 days

Category

Treatment - Drugs

2**Description**

Group 2 : Placebo agent, 10mg Daily, for 10 days

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Rajaei hospital

Full name of responsible person

Nima Derakhshan

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Chamran Avenue
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor of Research, Shiraz University of
Medical Sciences

Full name of responsible person
Seyed Masoum Masoumpoor

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Zand Avenue

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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

Vice Chancellor of Research, Shiraz University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty