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 morerate 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 Glascow 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

Street address
Chamran Avenue
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Shiraz

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

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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