

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

A randomized controlled trial on the efficacy and safety of Metformin in severe traumatic brain injury

Protocol summary

Study aim

To investigate safety and efficacy of Metformin in severe traumatic brain injury (TBI) patients

Design

single-center, single-blind, parallel-group, randomized controlled trial

Settings and conduct

The study took place in the intensive care unit (ICU) of the Sina Hospital in Tehran, Iran in severe TBI patients. Blood sampling from the eligible patients for the measurement of efficacy biomarkers was performed on admission and at 24h, 48h, 72h and 120h post-allocation in all study patients and for pharmacokinetic parameters samples were obtained at 0.5h, 1h, 2h, 4h, 8h and 12h post-intervention in the intervention group. Based on the unconsciousness of the patients (GCS of 8 or less), the study was single blinded.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: definite diagnosis of head trauma, GCS score of 8 or less, an age of 18 to 65 years, and written signed informed consent Main exclusion criteria: time of admission to ICU of more than 48 hours, lab data out of the ranges in protocol, NPO status, diabetes, previous treatment with metformin

Intervention groups

Intervention: 1g metformin b.i.d at 12h intervals for 5 consecutive days and usual management Control: usual management of severe TBI

Main outcome variables

Primary: 5-day post-trauma serum concentration profile of S100B Secondary: 5-day post-trauma serum concentration profile of GFAP and NLR; Safety; Pharmacokinetic parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180803040681N1**

Registration date: **2018-10-20, 1397/07/28**

Registration timing: **retrospective**

Last update: **2018-10-20, 1397/07/28**

Update count: **0**

Registration date

2018-10-20, 1397/07/28

Registrant information

Name

Ali Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8163 3047

Email address

a-taheri@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2016-05-01, 1395/02/12

Actual recruitment end date

2018-06-01, 1397/03/11

Trial completion date

2018-07-06, 1397/04/15

Scientific title

A randomized controlled trial on the efficacy and safety of Metformin in severe traumatic brain injury

Public title

Metformin in severe traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

a definite diagnosis of head trauma GCS score of 8 or less patients on mechanical ventilator written informed consent signed by patient's legal guardian

Exclusion criteria:

time of admission to ICU of more than 48 hours Nil Per Os (NPO) status on admission day diabetes previous treatment with metformin or any other biguanide medication blood glucose level of ≥ 150 mg/dL or ≤ 70 mg/dL simultaneous participation in another clinical trial serum creatinine level of 1.5mg/dL or more serum lactate level of 2.5mmol/L or more arterial pH of less than 7.25 serum bicarbonate of 13mEq/L or less moderate to severe renal impairment (estimated glomerular filtration rate (eGFR) of below 45mL/min/1.73m²) cirrhosis acute liver failure

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization sequence was created using R-3.2.3 statistical software. Eligible patients were randomly assigned to study groups in a 1:1 ratio using random block sizes of 2 and 4.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are not mentally oriented as their GCS score is 8 or less.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Poursina Ave., Qods Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417614411

Approval date

2016-04-12, 1395/01/24

Ethics committee reference number

IR.TUMS.REC.1395.2380

Health conditions studied

1

Description of health condition studied

Severe Traumatic Brain Injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

The 5-day post-trauma serum concentration profile of S100B to evaluate the prognosis of study groups

Timepoint

On admission and at 24h, 48h, 72h and 120h post-allocation

Method of measurement

ELISA kit

Secondary outcomes

1

Description

5-day post-trauma serum concentration profile of GFAP

Timepoint

On admission and at 24h, 48h, 72h and 120h

Method of measurement

ELISA kits

2

Description

5-day post-trauma serum concentration profile of NLR

Timepoint

On admission and at 24h, 48h, 72h and 120h

Method of measurement

ELISA kits

3

Description

Pharmacokinetic parameters

Timepoint

0.5h, 1h, 2h, 4h, 8h and 12h post-intervention

Method of measurement

Ultra High Performance Liquid Chromatography coupled to mass spectrometry

4

Description

Safety

Timepoint

Throughout hospital stay

Method of measurement

Monitoring; Lab data

Intervention groups

1

Description

Intervention group: 1g metformin two times a day at twelve-hour intervals for five consecutive days through a nasogastric tube and usual management at the discretion of the critical care team

Category

Treatment - Drugs

2

Description

Control group: usual management at the discretion of the critical care team

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

intensive care unit (ICU) of the Sina University Teaching Hospital

Full name of responsible person

Mojtaba Mojtahedzadeh

Street address

Hassanabad Sq., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ramin Heshmat

Street address

Shariati hospital, Kargar Ave., Tehran, Iran

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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

Tabriz 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

Tehran University of Medical Sciences

Full name of responsible person

Mojtaba Mojtahedzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Ali Taheri

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All collected deidentified IPD

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

People working in academic institutions People working in businesses

Under which criteria data/document could be used

Without limitations in case of citing the study article

From where data/document is obtainable

Via E-mail: a-taheri@student.tums.ac.ir

What processes are involved for a request to access data/document

Stating the objective of requesting the data

Comments