

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

effects of citicoline on the healing process of patients with traumatic concussion

Protocol summary

Study aim

the aim of this study is to evaluate the effects of citicoline on the healing process of patients with severe TBI hospitalized in the ICU and neurosurgery departments of Imam Reza hospital in Birjand.

Design

This double-blind randomized clinical trial will perform on 30 patients. The patients will be randomly distributed into three groups.

Settings and conduct

This study is a clinical trial in patients aged 5 to 60 years with isolated and severe TBI (GCS less than or equal to 8) referred to ICU and Neurosurgery departments. Before the study, the goals and stages of the study will be fully explained to patients and informed oral consent will be obtained from patients who wish to participate in the study. All patients will be randomly distributed into three groups of A, B or C by choosing one card from A, B or C cards. The study is a double-blind study in which only the physician is aware of the distribution of patients into three different groups, and patients, nurses, and researchers who collect all the data are unaware.

Participants/Inclusion and exclusion criteria

All patients with severe TBI with GCS lower or equal to 8 hospitalized in ICU and Neurosurgery ward with age between 5 to 60 years will be included in the study and patients with severe cognitive disorders, severe systemic disorder, those with penetrating skull trauma or open skull trauma, or severe chest or lung trauma, subdural or large epidural hematoma requiring surgery and pregnant women will be excluded.

Intervention groups

using IV Citicoline during hospitalization. patients were randomly distributed into three groups of A (control), B (citicoline with a dosage of 0.5 gr/ twice a day) and C (citicoline with a dosage of 1.5 gr/ twice a day).

Main outcome variables

GCS; the degree of muscle strength; GOS; contusion volume and cerebral edema; patients' dependency on a

ventilator; length of stay in ICU

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140611018063N7**

Registration date: **2020-03-21, 1399/01/02**

Registration timing: **retrospective**

Last update: **2020-03-21, 1399/01/02**

Update count: **0**

Registration date

2020-03-21, 1399/01/02

Registrant information

Name

Ali Rajabpour Sanati

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research - Birjand University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-02-06, 1395/11/18

Actual recruitment start date

2016-05-21, 1395/03/01

Actual recruitment end date

2017-02-06, 1395/11/18

Trial completion date

2017-02-06, 1395/11/18

Scientific title

effects of citicoline on the healing process of patients with traumatic concussion

Public title

Effects of Citicoline in patients with traumatic concussion

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Traumatic Head concussion GCS lower or equal to 8
Hospitalized in ICU and Neurosurgery ward Age between 5 to 60 years

Exclusion criteria:

severe cognitive disorders severe systemic disorder
penetrating or open skull trauma severe chest or lung
trauma subdural or large epidural hematoma requiring
surgery younger than 5 or older than 60 years pregnant
women

Age

From **5 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

All the patients will be distributed randomly into three groups of A, B or C by randomly choosing one card marked with A, B or C out of 30 cards.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study was a double-blind study, in which only the physician was aware of the distribution, and the patient, nurse, and researchers collecting information were unaware of the distribution into three groups. Access to the patient records will be prevented from the patient's nurse and the researchers. Only the physician will be aware of patient records.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

ethics committee of Birjand University of Medical Sciences

Street address

Moallem Blvd

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Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2016-03-12, 1394/12/22

Ethics committee reference number

IR.BUMS.Rec.1394.438

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

head trauma

ICD-10 code

S06.2

ICD-10 code description

Diffuse brain injury

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

level of consciousness in a patients

Timepoint

First 7 days and on 14th day of hospitalization

Method of measurement

Glasgow Coma Scale scoring system

2**Description**

Muscle strength degree

Timepoint

The first week, on day 14, 21 and 30 of hospitalization

Method of measurement

Manual Muscle Testing scale

3**Description**

Contusion volume and cerebral edema

Timepoint

Days 1, 3, 5 and 7

Method of measurement

Computed Tomography scans

4**Description**

length of dependency on a ventilator

Timepoint

30 days of hospitalization

Method of measurement

Documentary Registry Data

5**Description**

stay length in the intensive care unit

Timepoint

30 days of hospitalization

Method of measurement

Documentary Registry Data

Secondary outcomes

empty

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

Intervention group 1: In this groups, the patients will be treated with received intravenous (IV) citicoline with a dosage of 0.5 gr/ twice a day(group B) and the treatment period will be 14 days.

Category

Treatment - Drugs

2**Description**

Intervention group 2: In this group, the patients will be treated with received intravenous (IV) citicoline with a dosage of 1.5 gr/ twice a day(group C) and the treatment period will be 14 days.

Category

Treatment - Drugs

3**Description**

Control group: the patients in this group will not receive citicoline and Only receive instilled sterile water as placebo.

Category

Placebo

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

Emam Reza Educational Hospital

Full name of responsible person

Dr. Jalal Ahmadi

Street address

Neurosurgery Ward, Emam Reza Educational Hospital, Taleghani Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Asghar Zarban

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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

Birjand University of Medical Sciences

Proportion provided by this source

1

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**

Person responsible for general inquiries**Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Soroush Hozeifi

Position

School of Medicine, Birjand University of Medical Sciences, Birjand, Iran

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

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Web page address<http://www.bums.ac.ir>**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

Ali Rajabpour-sanati

Position

School of Medicine, Birjand University of Medical Sciences, Birjand, Iran

Latest degree

Medical doctor

Other areas of specialty/work

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Web page address<http://www.bums.ac.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Jalal Ahmadi

Position

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Web page address**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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The entire statistical data from this study can be shared as needed based on the ethics committee's criteria.

When the data will become available and for how long

The results of this study, after publishing the results as a paper, will be published and shared.

To whom data/document is available

The data from this study will be available to all researchers.

Under which criteria data/document could be used

All academic researchers, in the form of research projects approved by the Ethics Committee, are allowed

to access the data and perform the necessary analyzes on the documentation of this research.

From where data/document is obtainable

Applicants for obtaining documentation of this study can request information by email with the corresponding author.

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

Applicants for obtaining documentation of this study can request information by email with the corresponding author.

Comments