Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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 epidoral 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 researches. 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
City
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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Web page address
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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

Academic

http://www.bums.ac.ir

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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jahmadi@bums.ac.ir

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