Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Citicoline on Barthel Index in Patients with Moderate and Severe Traumatic Brain Injury

Protocol summary

Study aim
Effect of citicoline on barthel index in patients with moderate and severe brain traumatic injury

Design
This study is a randomized clinical trial of double blind in which patients (80 patient) were Random Allocation software to use control groups in two groups.

Settings and conduct
This study will be performed in Kashani Medical Center. Patients and researchers will not be aware of the patient group and clinical care giver will only recognize the patients in the control and case group and will perform the intervention.

Participants/Inclusion and exclusion criteria
Patients with severe and moderate traumatic brain injury based on GCS less than 12 Patients should be without traumatic major lesions in the thorax, abdomen, and limbs Patients without heart problems Have the satisfaction to enter the study Previous history of brain Injury, stroke, or neurological disease Contraindications or sensitivity to Citicoline The presence of comorbidities such as cardiovascular, renal, hepatic, and malignant history Traumatic brain injury, major trauma to the thorax, abdomen and organs Unstable hemodynamics Surgical interventions were performed within the first 24 hours after trauma cardiopulmonary resuscitation was performed within the first 24 hours after trauma Dissatisfaction of the patient to enter the study and her/his death during the study

Intervention groups
The case group will be treated with citicoline with a dose of 2000 mg and twice daily as an injection for 1 week and 2000 mg oral twice daily. Patients in the control group were treated with placebo twice daily for 2 weeks.

Main outcome variables
Index Bartel (quality of life in patients with brain trauma)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200609047706N1**
Registration date: **2020-06-16, 1399/03/27**
Registration timing: **prospective**

Last update: **2020-06-16, 1399/03/27**
Update count: **0**

Registration date
2020-06-16, 1399/03/27

Registrant information
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Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-06-21, 1399/04/01
Expected recruitment end date
2021-01-20, 1399/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Effect of Citicoline on Barthel Index in Patients with Moderate and Severe Traumatic Brain Injury

Public title
Citicoline on Barthel Index in Patients with Moderate and Severe Traumatic Brain Injury
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with severe and moderate traumatic brain injury based on GCS less than 12 Patients should be without traumatic major lesions in the thorax, abdomen, and limbs Patients without heart problems Have the satisfaction to enter the study
Exclusion criteria:
Previous history of brain Injury, stroke, or neurological disease Contraindications or sensitivity to Citicoline The presence of comorbidities such as cardiovascular, renal, hepatic, and malignant history Traumatic brain injury, major trauma to the thorax, abdomen and other organs Unstable hemodynamics Pregnancy Surgical interventions were performed within the first 24 hours after trauma cardiopulmonary resuscitation was performed within the first 24 hours after trauma Dissatisfaction of the patient to enter the study and her/his death during the study
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the patient do not know he/ she is in which group (case or control) and the researcher do not know case qroup in research time and the clinical care giver has a list about case group and do the intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciense, Hezarjarib Ave
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-05-02, 1399/02/13
Ethics committee reference number
IR.MUI.MED.REC.1399.108

Health conditions studied

1

Description of health condition studied
Patients with severe and moderate brain injury
ICD-10 code
S06.2X
ICD-10 code description
Diffuse traumatic brain injury

Primary outcomes

1

Description
Improving the patient's barthel index
Timepoint
Upon arrival, one month, three months and six months
Method of measurement
Barthel Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Case group: citicoline drug at a dose of 2000 mg oral twice daily by injection for 1 week and 2000 mg twice daily orally
Category
Treatment - Drugs

2

Description
Control group: Taking placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashani Hospital
Full name of responsible person
Mehdi Mahmoodkhani
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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Isfahan

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

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehdi Mahmoodkhani
Position
Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available