

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

Name

MohammadReza Hasas

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3434 7398

Email address

mrh13691990@gmail.com

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 group 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	<u>1</u> 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 <u>1</u> 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 <u>1</u> 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 <u>1</u> 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 <u>2</u> 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

Street address

Kashani Hospital. Kashani Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3233 0091

Email

kashani@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoui Javanmardi

Street address

Isfahan University of Medical Science, Hezarjarib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

Isfahanuni@mui.ca.ir

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

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Kashani Hospital, Kashani Ave

City

Isfahan

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3233 0091

Email

mahmoodkhani@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Mahmoodkhani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Kashani Hospital, Kashani Ave

City

Isfahan

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3233 0091

Email

kashani@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Reza Hassas

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Alzahra Hospital, Sofeh Ave

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3434 7398

Email

alzahra@mui.ac.ir

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