

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of cerebrolysin on patients with head trauma and diffuse axonal injury

Protocol summary

Tabriz University of Medical Sciences

Summary

The aim of this study is evaluation of effect of cerebrolysin on prognosis of patients with head trauma and DAI patients older than 18 yrs admitted to hospital in 48 hours after trauma .52 patients are divided to 2 subgroups randomly. Patients in control group receive 10cc of cerebrolysin intravenously for 10 days and GCS of patients on admission, 24 and 48 hours later, one week later and at the time of discharge and GOS are compared.

Expected recruitment start date

2014-05-09, 1393/02/19

Expected recruitment end date

2014-08-21, 1393/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Scientific title

The effect of cerebrolysin on patients with head trauma and diffuse axonal injury

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040312888N2**

Registration date: **2014-05-20, 1393/02/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-20, 1393/02/30

Registrant information

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Name of organization / entity

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Public title

The effect of cerebrolysin on patients with head trauma and brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with age between 18 to 80 and traumatic brain injury and DAI, admitted to hospital before 48 hours from trauma. Exclusion criteria: Severe renal, liver, respiratory or heart disease, loss of consciousness because of drug or alcohol, history of CVA, pregnancy, patients with multi trauma which are life threatening, evidences of malfunction of brainstem, evidences of status epilepticus or epilepsy

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Recruitment status

Recruitment complete

Funding source

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Deputy of Faculty Medicine

Street address

3rd floor of 2nd central bulding of Tabriz university of
Medical Sciences, Daneshghah Ave. Tabriz

City

Tabriz

Postal code

3357310112

Approval date

2014-02-21, 1392/12/02

Ethics committee reference number

92211

2

Ethics committee

Name of ethics committee

Research Deputy of Faculty Medicine

Street address

3rd floor of 2nd central bulding of Tabriz university of
Medical Sciences, Daneshghah Ave. Tabriz

City

Tabriz

Postal code

3357310112

Approval date

2014-02-21, 1392/12/02

Ethics committee reference number

92211

Health conditions studied

1

Description of health condition studied

Diffuse brain injury

ICD-10 code

s06.2

ICD-10 code description

Primary outcomes

1

Description

prognosis of patients

Timepoint

discharge time

Method of measurement

Questionnaire

2

Description

prognosis of patients

Timepoint

discharge time

Method of measurement

Questionnaire

Secondary outcomes

1

Description

GCS,GOS

Timepoint

Admission,24 and 48 hours later,discharge

Method of measurement

Questionnaire

2

Description

GCS,GOS

Timepoint

Admission,24 and 48 hours later,discharge

Method of measurement

Questionnaire

Intervention groups

1

Description

Placebo,Sterile water,10 cc,IV,10 days

Category

Treatment - Drugs

2

Description

Cerebrolysin,10 cc,IV,10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Educational and Training Hospital
Full name of responsible person
Nayer Ebrahimi
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Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Asgari Mohammad
Street address
Tabriz University of Medical Sciences,Golgasht
City
Tabriz
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
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Asgari Mohammad
Street address
Tabriz University of Medical Sciences,Golgasht

City
Tabriz
Grant name
Grant code / Reference number
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Tabriz University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty