Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of cyclosporine-A on neuro-recovery of diffuse axonal injury in comparison with placebo.

Protocol summary

Summary

1) Objective: To evaluate the efficacy of Cyclosporine-A(CsA) in improvement of consciousness and cognitive dysfunction of patients with diffuse axonal injury(DAI) after Traumatic Brain Injury(TBI). 2) Design: This study is designed as a randomized double-blind placebo-controlled with 100 patients suffered from DAI after TBI. 3) Setting and conduct:100 patients that suffered from DAI after Traumatic Brain Injury are underwent the study if consent form is completed by first relatives and all of them had inclusion criteria of the study. 4) Participants including major eligibility criteria Inclusion criteria are: Age between 16 and 75 years; Glasgow coma scale(GCS) score less than 10 in 24 hours of admission; Complete consent form; βHCG is negative and no pregnant patients. Exclusion criteria are: Negative brain stem reflex response; Patients with immune deficiency; Liver and kidney diseases; Penetrative brain injury; Multiple trauma; Past medical history of cancer; And patients that need emergency surgery; Pregnant women 5) Intervention: 100 patients that included to this study are divided to 2 groups, Cyclosporine group and Placebo group, by randomized double blinded fashion. In first 8 hours of admission, Cyclosporine A was administered to the Cyclosporine group (n=50) as 5 mg/kg/24h via 250 ml dextrose water 5% solution(DW5%) during the first eight hours after trauma. The control group (n=50) received only DW5% in the same course. 6) Main outcome measures(variables): GCS, GOS-E and MMSE tests that are evaluated in both groups on discharge time, 3 and 6 months after trauma.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011712164N1**
Registration date: **2013-02-16, 1391/11/28**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-02-16, 1391/11/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Isfahan University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cyclosporine-A on neuro-recovery of diffuse axonal injury in comparison with placebo.

Public title

The Effect of Cyclosporine on Head Trauma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are: Age between 16 and 75 years; GCS score less than 10 in 24 hours of admission; Complete consent form; βHCG is negative and no pregnant patients. Exclusion criteria are: Negative brain stem reflex response; Patients with immune deficiency; Liver and kidney diseases; Penetrative brain injury; Multiple trauma; Past medical history of cancer; And patients that need emergency surgery; Pregnant women

Age

From **16 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

The Ethics Committee of Isfahan University of Medical Sciences

Street address

The Ethics Committee Department, Library builiding, Isfahan University of Medical Scieces, Hezar Jareeb Ave

City

Isfahan

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

390356

Health conditions studied

1

Description of health condition studied

Diffuse Axonal Injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse Brain Injury

Primary outcomes

1

Description

Level of Consciousness

Timepoint

1day, 3month, 6month

Method of measurement

GCS, GOS-E, MMSE

Secondary outcomes

1

Description

Liver Function Tests

Timepoint

12hour, 24hour, 36hour, 48hour, 4day, 7day, 3month, 6month

Method of measurement

AST(Aspartat Aminotransferase), ALT(Alanine Aminotransferase), ALP(Alkaline Phosphatase)

Intervention groups

1

Description

Cyclosporine-A, vial solution, 5mg/kg in 250 mili liter dextrose water 5% solution(DW5%) during the first 24hour of admission, one dose is administrated in all periods of the study.

Category

Treatment - Drugs

2

Description

Intravenous, slow infusion of 250 mili liter of dextrose water 5% solution(DW5%) during the first 24hour of admission, that this solution is administrated one time in all periods of the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Dr.Mehdi Mahmoudkhani

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2

Recruitment center
Name of recruitment center
Ayatolah Kashani Hospital
Full name of responsible person
Dr.Mohammad Motahari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Science
Full name of responsible person
Akram Mazaheri
Street address
No.4 building, Isfahan University of Medical Sciences, Hezar Jareeb St
City
Isfahan
Grant name
Grant code / Reference number
390356
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Isfahan University of Medical Science
Proportion provided by this source
100
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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Person responsible for updating data

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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