

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparative efficacy of Cyproheptadine and Baclofen on spasticity in patients with head trauma

Protocol summary

Summary

After obtaining written informed consent from the patient's family, and getting an approval from Ethics committee of Ahvaz Jundishapur University of Medical Sciences, 40 head trauma patients will take part in a single-blind prospective, randomized study to comparative efficacy of Cyproheptadine and Baclofen on spasticity in patients with head trauma. Inclusion criteria: patients with diffuse axonal injury without chronic hepatic or renal disease; 15 to 60 years old. Exclusion criteria: changing in treatment plan like surgery; drug reactions; drug side effects. Patients will be randomly allocated into two groups according to table of random numbers. Groups "one" and "two" will receive oral Cyproheptadine 2 mg/kg with oral Baclofen 25 mg/kg and oral Baclofen 25 mg/kg every eight hours for fifteen days, respectively. Both groups of patients are unaware of type of prescription drugs. Spasticity in patients in 1, 3, 6, 9, 12, 15 days, according to Modified Ashworth Scale is measured. Alaninetransaminase, Aspartate Aminotransferase, and Alkaline Phosphatase weekly, and Blood Urea Nitrogen, and Creatinine daily will measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041112777N1**

Registration date: **2014-05-13, 1393/02/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-13, 1393/02/23

Registrant information

Name

Soheil Fallahpour

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1374 3032

Email address

fallahpour.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz University of Medical Sciences

Expected recruitment start date

2014-08-22, 1393/05/31

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative efficacy of Cyproheptadine and Baclofen on spasticity in patients with head trauma

Public title

Comparative efficacy of Cyproheptadine and Baclofen on spasticity in patients with head trauma

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with diffuse axonal injury without chronic hepatic or renal disease; 15 to 60 years old. Exclusion criteria: Changing in treatment plan like surgery; drug reactions; drug side effects.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

No. 21, Ave. 1, Golestan Blvd.

City

Ahvaz

Postal code

61357-15794

Approval date

2012-06-09, 1391/03/20

Ethics committee reference number

ETH-490

Health conditions studied**1****Description of health condition studied**

Head Trauma

ICD-10 code

S07

ICD-10 code description

Multiple superficial injuries of head

Primary outcomes**1****Description**

Spasticity

Timepoint

1, 3, 6, 9, 12, 15 days

Method of measurement

Modified Ashworth Scale

Secondary outcomes**1****Description**

Alanine Transaminase (ALT)

Timepoint

Weekly

Method of measurement

U/ml

2**Description**

Blood Urea Nitrogen(BUN)

Timepoint

Daily

Method of measurement

Mg/dl

3**Description**

Aspartate Amino Transferase(AST)

Timepoint

Weekly

Method of measurement

U/ml

4**Description**

Alkaline Phosphatase(ALP)

Timepoint

Weekly

Method of measurement

U/ml

5**Description**

Creatinine

Timepoint

Daily

Method of measurement

Mg/dl

Intervention groups**1****Description**

Drugs: 1- Cyproheptadine: Dose: 2 mg/kg Number of using:Forty five times Factory name: Jalinus Country's Name: Iran Location prescribed: Oral Administration time: Every eight hours 2- Baclofen: Dose: 25 mg/kg Number of using: Forty five times Factory name: Mylan

Country's Name: England Location prescribed: Oral
Administration time: Every eight hours

Category

Treatment - Drugs

2

Description

Baclofen: Dose: 25 mg/kg Number of using: Forty five times
Factory name: Mylan Country's Name: England
Location prescribed: Oral Administration time: Every eight hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Educational Hospital

Full name of responsible person

Dr. Saleh Rasras

Street address

No. 307, Kokab Street, Masters Alley, Golestan Blvd.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Dr. Mostafa Fegghi

Street address

No. 21, Ave. 1, Golestan Blvd.

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

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

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Soheil Fallahpour

Position

Resident of Neurosurgery

Other areas of specialty/work

Street address

No. 12, Enghelab Chamber, Golestan Blvd.

City

Ahvaz

Postal code

Phone

+98 61 1374 3032

Fax

Email

Fallahpour.s@ ajums.ac.ir, Fatahi.m@ajums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Soheil Fallahpour

Position

Resident of Neurosurgery

Other areas of specialty/work

Street address

No. 12, Enghelab Chamber, Golestan Blvd.

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+98 61 1374 3032

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Fallahpour.s@ ajums.ac.ir, Fatahi.m@ajums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Web page address

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