

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of Amantadin and placebo(Acetaminophen) on the level of consciousness in patients with traumatic brain injury with an average level of consciousness

Protocol summary

Summary

The aim of the purpose of this study was to increase the level of consciousness of patients with traumatic brain injury with Amantadine . Entry rate (having a level of consciousness between 9 to 13; passing one day of gavage; absence of kidney and other diseases; lack of susceptibility to Amantadine ; non-pregnancy; Spinal cord; Outcome criteria: patient's death; length of study; incidence of drug poisoning; cardiac and respiratory arrest; incidence of renal scar tissue; seizure; absence of coagulation problems). Research community of patients with cerebral trauma with moderate level of consciousness in Golestan Hospital Ahvaz .The samples is 96 patients who were non -randomized divided into two groups of 48 (Amantadine) and Acetaminophen (placebo). Intervention of oral administration of 200 mg Amantadine and oral 200 mg of placebo (oral Acetaminophen). During a week, the daily dose is taken as a gavage. The time required for sampling is one month. The variables are the initial outcomes of changes in the level of consciousness of both groups in the first, second, third and fourth weeks after the administration of the drug.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061634573N1**
Registration date: **2017-08-16, 1396/05/25**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-16, 1396/05/25

Registrant information

Name

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Name of organization / entity

Ahvaz Jundishapoor University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapoor University of Medical Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2016-04-18, 1395/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Amantadin and placebo(Acetaminophen) on the level of consciousness in patients with traumatic brain injury with an average level of consciousness

Public title

The effect of Amantadin on the level of consciousness in patients with traumatic brain injury with an average level of consciousness on arrival at the Golestan hospital in 1395 and 1396

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion:level of consciousness between 9 and 13 ; arrived a day gavage ; absence of kidney damage and other diseases ; are not sensitive to amantadine ; no pregnancy, no injury ;having age between 18 to 60 - Exclusion criteria: expair patient during the study ; drug toxicity ; cardiac arrest ; respiratory and renal damage in patients; with surgical complications and seizure ; of clotting problems ; maxillofacial trauma

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Not 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

Department of Development Research and Technological University Jundishapoor of Medical Sciences

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Ahvaz University Jundishapoor of Medical Sciences- Department of Development Research and Technological - Ahvaz

City

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Postal code

1579461457

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

ir.ajums.Rec.1396.141

Health conditions studied

1

Description of health condition studied

Traumatic brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse brain injury

Primary outcomes

1

Description

Level of consciousness

Timepoint

after arrival at the unit-one week ,two weeks , after starting the drug

Method of measurement

Glasgow Coma Scale

Secondary outcomes

empty

Intervention groups

1

Description

Drug therapy in the control group (Amantadine tablets 200 mg) and case group (Acetaminophen200)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital in Ahvaz

Full name of responsible person

Behrooz Zarasvand

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17 Unit- Arshia Building-Dey-Ordibehesht Street- Golestan-Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapoor University of Medical Sciences

Full name of responsible person

Dr Mohammad Taghi Mansoori

Street address

Ahvaz University Jundishapoor of Medical Sciences

City

Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jundishapoor 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

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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