Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ofThe 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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapoor University of Medical Sciences
Full name of responsible person
Dr Mohammaf Taghi Mansoori
Street address
Ahvaz University Jundishapoor of Medical Sciences
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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

Name of organization / entity

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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