Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Gabapentin (vs. placebo) in improvement of consciousness level of traumatic brain injury patients

Protocol summary

Summary

This is a triple blind randomized clinical trial and the aim of this study was evaluation of Gabapentin in improvement of consciousness level of traumatic brain injury patients. 60 patients with these criteria were enrolled: The patients who suffered from moderate (9 <=GSC>12) and severe (GCS<9) traumatic brain injury and diffuse axonal injury were included. The exclusion criteria were: the patient death during the study and the patients who did not tolerate gabepentin or present its severe side effects. The Patients were randomized to receive 300 mg Gabapentin or placebo twice a day for two weeks. Before treatment and twice during this period and at the first outpatient referral the patients were followed and be examined for probable problems or drug side effects. and GCS (Glasgow Coma Scale) and GOS (Glasgow outcome scale) were determined and EEG (Electroencephalogram) recording is done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009204786N1**
Registration date: **2010-11-12, 1389/08/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-11-12, 1389/08/21

Registrant information

Name
Seyed Ali Sonbolestan
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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sonbolestan@edc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan university of medical sciences

Expected recruitment start date

2008-03-20, 1387/01/01

Expected recruitment end date

2009-08-23, 1388/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Gabapentin (vs. placebo) in improvement of consciousness level of traumatic brain injury patients

Public title

The effect of Gabapentin in traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

The patients who suffered from moderate (9 <=GSC>12) and severe (GCS<9) traumatic brain injury and diffuse axonal injury were included. The exclusion criteria were: the patient death during the study and the patients who did not tolerate gabepentin or present its severe side effects.

Age

No age limit

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan university of medical sciences - Isfahan neuroscience research center
Street address
Hezar jerib St.
City
Isfahan
Postal code
Approval date
2010-10-30, 1389/08/08
Ethics committee reference number
051/24/1034

Health conditions studied

1

Description of health condition studied
Diffuse brain injury
ICD-10 code
S06.2
ICD-10 code description
Diffuse brain injury

Primary outcomes

1

Description
Glasgow Coma Scale
Timepoint
before intervention, 1 and 2 weeks after intervention onset, at the first outpatient referral
Method of measurement
Physical examination

2

Description
Glasgow outcome scale
Timepoint
before intervention, 1 and 2 weeks after intervention onset, at the first outpatient referral
Method of measurement
Physical examination

Secondary outcomes

1

Description
Electroencephalography
Timepoint
before intervention, 1 and 2 weeks after intervention onset, at the first outpatient referral
Method of measurement
Electroencephalography

Intervention groups

1

Description
The intervention group is treated by 300 mg Gabapentin twice daily
Category
Treatment - Drugs

2

Description
The control group is treated by placebo twice daily
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani hospital
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellery for research, Isfahan university of medical sciences
Full name of responsible person
Dr. Peiman Adibi
Street address

Hezar jerib St.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellery for research, Isfahan 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

Isfahan university of medical sciences

Full name of responsible person

Seyed Ali Sonbolestan

Position

Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mohammad reza Najafi

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Associated professor of Neurology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Isfahan university of medical sciences

Full name of responsible person

Seyed Ali Sonbolestan

Position

Other areas of specialty/work

Street address

City

Isfahan

Postal code

Phone

Fax

Email

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