

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 ( $9 \leq \text{GSC} < 12$ ) and severe ( $\text{GCS} < 9$ ) 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1233 1401

###### Email address

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 ( $9 \leq \text{GSC} < 12$ ) and severe ( $\text{GCS} < 9$ ) 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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**Full name of responsible person**

Dr. Mohammad reza Najafi

**Position**

Associated professor of Neurology

**Other areas of specialty/work**

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Seyed Ali Sonbolestan

**Position**

**Other areas of specialty/work**

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Isfahan

**Postal code**

**Phone**

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**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*