Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Compare of The efficacy of Pregabaline and Carbamazepine on patients with Trigeminal Neuralgia

Protocol summary

Study aim

Evaluation of Pregabaline efficacy in patients with Trigeminal Neuralgia

Design

In the study twenty patients suffering from idiopathic trigeminal neuralgia are selected according to international headache society criteria. They are assigned randomly in two similar groups with ten patients in each group. Patients in group one take Pregabaline seventy five milligrams twice daily for thirty days and patients in Group two takes Carbamazepine two hundred milligrams twice daily for thirty days. After five days free interval without drug patients in group one take Carbamazepine and patients in group two take Pregabaline for the same dose and period. Selection the group of first patient is by lottery and next cases alternately are assigned in two groups.

Settings and conduct

Study will accomplish in neurology clinic of Mostafa Khomeini hospital. Study design is explained to all patients and all of them have written consent according to instructions of ethical committee of Shahed University. All drugs are put in uniform packages and special code is assigned to each one. Patients, main researchers and assessors are not aware of drugs kind and patient's group. All data are recorded and groups compared each other with statistical analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between eighteen to seventy-five years old. Suffering from idiopathic Trigeminal neuralgia according to international headache society criteria. Exclusion criteria: Patients with other kinds of head and facial pain. History of psychiatric problems, liver failure, renal failure, heart failure, thrombocytopenia, leukopenia, anemia and malignancy. Pregnancy and breast feeding.

Intervention groups

Group one of patients takes Pregabaline seventy- five milligrams twice daily for thirty days and Group two takes Carbamazepine two hundred milligrams twice daily for thirty days. After five days interval free of drugs group One of patients take Carbamazepine and group two takes Pregabaline for the same dose and period. Selection the group of first patient is by lottery and next cases alternately are assigned in two groups.

Main outcome variables

Pain intensity is evaluated by Visual analogue scale and 5-points verbal rating scale before starting and in the twenty-eight to thirtieth day of each cycle. Frequency of repeat of pain attacks before starting and in the day twenty- eight to thirtieth of each cycle.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161103030680N7**
Registration date: **2018-01-28, 1396/11/08**
Registration timing: **retrospective**

Last update: **2018-01-28, 1396/11/08**
Update count: **0**

Registration date

2018-01-28, 1396/11/08

Registrant information

Name

Siamak Afshinmajd

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 9438

Email address

afshin@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2015-12-22, 1394/10/01
Expected recruitment end date
2017-12-22, 1396/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Compare of The efficacy of Pregabaline and Carbamazepine on patients with Trigeminal Neuralgia

Public title
Efficacy of Pregabaline on Trigeminal Neuralgia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between eighteen to seventy-five years old. Suffering from Idiopathic Trigeminal neuralgia according to International Headache Society criteria.
Exclusion criteria:
Suffering from other kinds of head and facial pain History of psychiatric diseases, Renal failure, liver failure, Heart failure, Thrombocytopenia, Leuckopenia, Anemia and malignancy Pregnancy and Breast feeding
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
All selected samples are given one number and then are assigned in two groups alternatively by use of random number chart. group one take Pregabaline for thirty days and group two take Carbamazepine for the same period. After five days interval without any drug patients in group one take Carbamazepine and patients in group two take Pregabaline for the same period. Selection of group for the first patient is by lottery.
Blinding (investigator's opinion)
Double blinded
Blinding description
All drugs are inserted in uniform packages and mark by specific code . Drugs are given to patients in the way that,participipitants ,main researchers and assessors of signs and symptoms from all groups such as physicians or students are not aware of patient 's group and the kind of drugs. Study design and steps are explained for all patients but they are not aware of their group and drug kind which started for them.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of Shahed University
Street address
Entrance of Tehran - Qom highway
City
Tehran
Province
Tehran
Postal code
3319118651
Approval date
2015-11-16, 1394/08/25
Ethics committee reference number
Shahed.REC.1394.65

Health conditions studied

1

Description of health condition studied
Trigeminal Neuralgia
ICD-10 code
G50.0
ICD-10 code description
Trigeminal neuralgia

Primary outcomes

1

Description
Neuralgic pain intensity
Timepoint
Before starting the drugs and from days twenty- eight to thirtieth in each period
Method of measurement
Visual Analogue scale (VAS)

2

Description
Neuralgic pain intensity
Timepoint

Before starting the drugs and from days twenty- eight to thirtieth in each period

Method of measurement

5 points verbal rating scale

3

Description

Duration of neuralgic pain

Timepoint

Before starting the drugs and from days twenty- eight to thirtieth in each period

Method of measurement

Average duration of attacks in seconds

4

Description

Frequency of neuralgic pain

Timepoint

Before starting the drugs and from days twenty- eight to thirtieth in each period

Method of measurement

Number of attacks in one day

Secondary outcomes

1

Description

Unpredictable drug reactions (Pruritus, Burning sensation, Skin redness)

Timepoint

immediately after patient alarm

Method of measurement

Observation, Examination, and refer to the specialist.

2

Description

Drowsiness

Timepoint

Immediately after patient alarm

Method of measurement

Observation, examination, and refer to the specialist.

Intervention groups

1

Description

First group: Ten patients who assigned randomly in this group take Pregabaline seventy-five milligrams two times daily for thirty days. After five days interval without any drug these patients take Carbamazepine two hundred milligrams every twelve hours for thirty days.

Category

Treatment - Drugs

2

Description

First group: Ten patients who assigned randomly in this group take Carbamazepine two hundred milligrams two times daily for thirty days. After five days interval without any drug these patients take Pregabaline seventy five milligrams two times daily for thirty days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mostafa Khomeini Hospital

Full name of responsible person

Siamak Afshinmajd

Street address

Italia street. Keshavarz Blvd

City

Tehran

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Tehran

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1416643491

Phone

+98 21 8896 9438

Email

safshinmajd@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Zahra Kiasalari

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3319118651

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Email

kiasalari@shahed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Siamak Afshinmajd
Position
associate professor of neurology
Latest degree
Specialist
Other areas of specialty/work
Neurology
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Person responsible for scientific inquiries

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Specialist
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available