Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The camparison of therapeutic effect of carbamazepine and combination therapy with gabapentin and baclofen, in the treatment of trigeminal neuralgia.

Protocol summary

Summary

Purpose: The comparison of therapeutic effect of carbamazepin and combination therapy with gabapentin and baclofen in trigeminal neuralgia Main inclusion criteria: Patients with trigeminal neuralgia Main exclusion criteria: Patients with trigeminal neuralgia and other systemic diseases Study group: Patients with trigeminal neuralgia referred to yazd dental school Sample size: 40 people Study intervention: Carbamazepin 200 milligram 3 times daily, Gabapentin 100 milligram and Baclofen 10 milligram 3 times daily Timing: 4 months Primary outcome measure: clinical functional score, pain intensity changes

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202219103N1**
Registration date: **2012-03-25, 1391/01/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-03-25, 1391/01/06

Registrant information

Name
Neda Gholami
Name of organization / entity
Yazd Shahid Sadoughi University of Medical Science, Dental school
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Iran (Islamic Republic of)
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drahadian@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Science

Expected recruitment start date

2012-01-10, 1390/10/20

Expected recruitment end date

2012-01-30, 1390/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The camparison of therapeutic effect of carbamazepine and combination therapy with gabapentin and baclofen, in the treatment of trigeminal neuralgia.

Public title

Carbamazepine effect in trigeminal neuragia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with trigeminal neuralgia
Exclusion criteria: Patients with trigeminal neuralgia and other systemic diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Yazd Shahid Sadoughi University of Medical Science

Street address
Central part of the Shahid Sadoughi University of Medical Science, Shahid Bahounar Square, Yazd, Iran

City
Yazd

Postal code
8916978477

Approval date
2012-01-04, 1390/10/14

Ethics committee reference number
171126895

Health conditions studied

1

Description of health condition studied
trigeminal neuralgia

ICD-10 code
G50.0

ICD-10 code description
Syndrome of paroxysmal facial pain Tic douloureux

Primary outcomes

1

Description
clinical functional score

Timepoint
1 week, 3 weak, 2 mounth, 3 mounth, 4 mounth

Method of measurement
1) same pain 2) tingling and shocking pain 3)tingling 4)complete resolve

2

Description
pain intensity changes

Timepoint
1 week, 3 weak, 2 mounth, 3 mounth, 4 mounth

Method of measurement
vas

Secondary outcomes

1

Description
drug side effects

Timepoint
3 weeks

Method of measurement
Laboratory tests

Intervention groups

1

Description
200 mg carbamazepine/oral/ 3 times daily / 4 mounths

Category
Treatment - Drugs

2

Description
100 mg gabapentin+ 10 mg baclofen / oral/ 3 times dailyl 4 mounths

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Yazd Shadid Sadoughi University of Medical Science, Dental School

Full name of responsible person

Street address

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd Shadid Sadoughi University of Medical Science, Dental School

Full name of responsible person
Fatemeh Ezodini

Street address
Yazd Shahid Sadoughi University of Medical Science,

Dental School, Fazaye sabz Crossroad, Dahe-fajr Blv, Yazd, Iran

City
Yazd

Grant name

Grant code / Reference number

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

Title of funding source
Yazd Shadid Sadoughi University of Medical Science, Dental School

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
Yazd Shadid Sadoughi University of Medical Science, Dental School

Full name of responsible person
Neda Gholami

Position
Post graduated student

Other areas of specialty/work

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Position
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Other areas of specialty/work

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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