

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The comparison 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 carbamazepine 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: Carbamazepine 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

Country

Iran (Islamic Republic of)

Phone

+98 35 1622 0022

Email address

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 comparison 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 Bahonar 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
daily/ 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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Full name of responsible person

Hakimeh Ahadian

Position

Specialist in Oral and Maxillofacial Medicine

Other areas of specialty/work

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Yazd Shadid Sadoughi University of Medical Science,
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Full name of responsible person

Neda Gholami

Position

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Other areas of specialty/work

Street address

City

Postal code

Phone

00

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