

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation and comparison of the effectiveness of Trigeminal nerve block and Gasserian ganglion block in patients with Trigeminal nerve neuralgia

Protocol summary

Study aim

Determining and comparing the effectiveness of two methods of peripheral Trigeminal nerve block with Gasserian ganglion block in patients with Trigeminal neuralgia

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 2 on 32 patients

Settings and conduct

In this randomized double-blind clinical trial, 32 eligible patients referred to Kashani and Al-Zahra hospitals in Isfahan will be included in the study and randomly divided into two groups. The first group will be under the trigeminal nerve block and the second group will be under the Gasserian ganglion block. Then the severity of pain and the location of pain will be compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age 18-65 years, having unilateral trigeminal neuralgia in the second, third, or both branches (approved by a neurologist), lack of proper response to medication, lack of coagulation disorders, lack of anatomical changes that It is not possible to do the block, no pregnancy and consent to enter the study. Exclusion criteria include Unsuccessful performance of blocks based on fluoroscopic criteria and having atypical pain.

Intervention groups

First intervention group: For the Trigeminal nerve block, after finding the pterygoid plate under fluoroscopic guide, 80 mg of triamcinolone and 100 mg of lidocaine in a volume of 10 ml are used. The second intervention group: For the Gasserian ganglion block, after passing the needle through the foramen oval under fluoroscopic guide, 10 mg lidocaine and 30 mg triamcinolone are used.

Main outcome variables

Pain score; Location of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N42**

Registration date: **2021-10-02, 1400/07/10**

Registration timing: **prospective**

Last update: **2021-10-02, 1400/07/10**

Update count: **0**

Registration date

2021-10-02, 1400/07/10

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-03-22, 1401/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the effectiveness of Trigeminal nerve block and Gasserian ganglion block in patients with Trigeminal nerve neuralgia

Public title

The effectiveness of Trigeminal nerve block and Gasserian ganglion block in patients with Trigeminal nerve neuralgia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-65 years Having unilateral trigeminal neuralgia in the second, third or both branches (approved by a neurologist) Lack of proper response to medication Absence of coagulation disorders Absence of anatomical changes that do not allow the block to be performed No pregnancy Satisfaction to enter the study

Exclusion criteria:

Unsuccessful performance of blocks based on fluoroscopic criteria Having atypical pain

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 32 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". These numbers are randomly divided into two groups A (first intervention) and B (second intervention). Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

To meet the blinding condition in the study, the anesthesiologist that was responsible for performing intubation did not take part in the collection of patients' information due to knowledge of the type of intervention in each of the two groups; however, the patient, the patient data collector, and the statistician were not aware of the type of intervention in two groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2021-01-17, 1399/10/28

Ethics committee reference number

IR.MUI.MED.REC.1399.955

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

Pain score

Timepoint

One hour, one week, two weeks, three weeks and four weeks after the intervention

Method of measurement

Visual Analog Scale (VAS)

2

Description

The place of pain

Timepoint

One hour, one week, two weeks, three weeks and four weeks after the intervention

Method of measurement

Observation (Reported by the patient)

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: For the Trigeminal nerve block, after finding the pterygoid plate under fluoroscopic guide, 80 mg of triamcinolone and 100 mg of lidocaine in a volume of 10 ml are used.

Category

Treatment - Other

2

Description

The second intervention group: For the Gasserian ganglion block, after passing the needle through the foramen oval under fluoroscopic guide, 10 mg lidocaine and 30 mg triamcinolone are used.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Mehran Rezvani Habibabadi

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Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

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2

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Mehran Rezvani Habibabadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Full name of responsible person

Mehran Rezvani Habibabadi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available