

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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		Secondary Ids
		empty
Public title	The effectiveness of Trigeminal nerve block and Gasserian ganglion block in patients with Trigeminal nerve neuralgia	Ethics committees
Purpose	Treatment	<u>1</u>
Inclusion/Exclusion criteria		Ethics committee
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	Name of ethics committee
Exclusion criteria:	Unsuccessful performance of blocks based on fluoroscopic criteria Having atypical pain	Ethics committee of Isfahan University of Medical Sciences
Age	From 18 years old to 65 years old	Street address
Gender	Both	Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
Phase	2	City
Groups that have been masked	- Participant - Investigator - Data analyser	Isfahan
Sample size	Target sample size: 32	Province
Randomization (investigator's opinion)	Randomized	Isfahan
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.	Postal code
Blinding (investigator's opinion)	Double blinded	8179964167
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.	Approval date
Placebo	Not used	2021-01-17, 1399/10/28
Assignment	Parallel	Ethics committee reference number
Other design features		IR.MUI.MED.REC.1399.955
		Health conditions studied
		<u>1</u>
		Description of health condition studied
		Trigeminal neuralgia
		ICD-10 code
		G50.0
		ICD-10 code description
		Trigeminal neuralgia
		Primary outcomes
		<u>1</u>
		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)
		<u>2</u>
		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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

rezvani@med.mui.ac.ir

2

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Mehran Rezvani Habibabadi

Street address

Anesthesiology Department, Kashani Hospital, Kashani Street.

City

Isfahan

Province

Isfahan

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Email

rezvani@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

Street address

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

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Isfahan

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8174673461

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dean@med.mui.ac.ir

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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Contact

Name of organization / entity
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Mehran Rezvani Habibabadi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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City
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Province
Isfahan
Postal code
8174675731
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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