Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+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
Isfehan

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
Street address
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
Shaghayegh Haghjooy Javanmard
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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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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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