Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Orthokin therapy and radiofrequency ablation in the treatment for idiopathic trigeminal neuralgia

Protocol summary

Study aim
Determination of the effect of orthokin therapy and radioactive apparatus in the treatment of idiopathic trigeminal neuralgia

Design
A phase 3 randomized, two-arm, single-blinded, parallel-group trial of 46 patients. Randomization was carried out using random allocation software (RAS) with concealed randomization sequence

Settings and conduct
A total of 46 patients with idiopathic trigeminal neuralgia will be recruited from the outpatient clinic of Imam Reza Hospital in Tabriz and assigned to two groups using the block randomization method. The first group will be received the injection of 2 ml of orthokine, 4 times (once a week) each with a dose of 2 milliliters under fluoroscopic guide through the foramen oval with 22 spinal needles. The second group will be undergoing radiofrequency ablation under a fluoroscopic guide. Participants will be blinded to the random assignment of respondents until the end of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Confirmation of idiopathic trigeminal neuralgia, based on diagnostic criteria of the International Headache Association, trigeminal neuralgic pain, with an intensity of 40 to 100 based on the visual analog scale of 100 mm Exclusion criteria: Bleeding disorders, active infection, type 2 diabetes, patients with pacemakers, patients with internal drug injection devices, neoplasm, drug addiction, psychopathy, drug sensitivity, pregnancy and lactation

Intervention groups
Intervention group 1: Injection of 2 ml of orthokine, 4 times (once a week) each with a dose of 2 milliliters under fluoroscopic guide through foramen oval with 22 spinal needles Intervention group 1: Radiofrequency ablation under the fluoroscopic guide

Main outcome variables
Pain intensity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190618043923N6**
Registration date: **2022-07-17, 1401/04/26**
Registration timing: **retrospective**

Last update: **2022-07-17, 1401/04/26**
Update count: **0**

Registration date
2022-07-17, 1401/04/26

Registrant information
Name
Dawood Aghamohammadi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-03-04, 1400/12/13
Expected recruitment end date
2022-06-20, 1401/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of Orthokin therapy and radiofrequency ablation in the treatment for idiopathic trigeminal neuralgia

Public title
Effect of Orthokin therapy and radiofrequency ablation in the treatment for idiopathic trigeminal neuralgia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of idiopathic trigeminal neuralgia, based on diagnostic criteria of the International Headache Association Trigeminal neuralgic pain, with an intensity of 40 to 100 based on the visual analog scale of 100 mm
Exclusion criteria:
Bleeding disorders Active infection Type 2 diabetes Patients with pacemaker Patients with internal drug injection devices Neoplasm Drug addiction Psychopathy Drug sensitivity Pregnancy and lactation
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be assigned to two groups using block randomization using random allocation software (RAS). The size of blocks is 4 including the equal numbers of each intervention of the study in each block and a 1:1 assignment ratio. Blocking will be performed by the non-involved person in data sampling and analysis. To conceal the assignment, the type of intervention will be written on a sheet of paper coding using the letters A and B and placed inside matted, consecutively numbered envelopes. The envelopes will be arranged according to the participants' entry into the intervention, and the type of group will be revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study is a single-blinded study. Participants will not be aware of the random allocation sequences.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave
City
Tabriz
Province
East Azarbaijan
Postal code
3678965158
Approval date
2022-03-02, 1400/12/11
Ethics committee reference number
IR.TBZMED.REC.1400.1213

Health conditions studied

1

Description of health condition studied
Idiopathic trigeminal neuralgia
ICD-10 code
G50.9
ICD-10 code description
Disorder of trigeminal nerve, unspecified

Primary outcomes

1

Description
Pain intensity
Timepoint
Pain intensity at the beginning of the study (before the intervention) and 7, 14 and 21 days after the start of intervention
Method of measurement
100-mm Visual Analogue Scale

2

Description
Analgesic consumption
Timepoint
Analgesic consumption at the beginning of the study (before the intervention) and 7, 14, and 21 days after the intervention
Method of measurement
Self-reported

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Injection of 2 ml of orthokine, 4 times (once a week) each with a dose of 2 milliliters under fluoroscopic guide through foramen oval with 22 spinal needles
Category
Treatment - Drugs

2

Description
Intervention group 1: Radiofrequency ablation under the fluoroscopic guide
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Dawood Aghamohammadi
Street address
Emam Reza hospital, Golgasht Str., Azadi Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
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Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
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Dawood Aghamohammadi
Position
Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available