Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of autologous conditioned serum (Orthokine) injection into the oval foramen in pain control in trigeminal neuralgia patients: a pilot study

Protocol summary

Study aim
Determination of the effect of autologous conditioned serum (Orthokine) injection into the Foramen ovale in controlling pain of trigeminal neuralgia patients
Design
One-armed open trial
Settings and conduct
A total of 10 patients with idiopathic trigeminal neuralgia will be enrolled in the palliative outpatient clinic of Emam Reza Hospital in Tabriz and will be treated with the Fluoroscopic guided injection of 2 milliliter autologous conditioned serum into the foramen ovale.
Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnosis of idiopathic trigeminal neuralgia; complaining of severe pain refractory to oral medications Exclusion criteria: bleeding disorders; drug addiction; drug sensitivity; psychopathy
Intervention groups
Intervention: Injection of 2 milliliter autologous conditioned serum in to foramen oval, three times a week apart
Main outcome variables
Pain intensity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190618043923N1**
Registration date: **2019-06-29, 1398/04/08**
Registration timing: **prospective**

Last update: **2019-06-29, 1398/04/08**
Update count: **0**
Registration date
2019-06-29, 1398/04/08

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
2019-08-23, 1398/06/01
Expected recruitment end date
2020-02-18, 1398/11/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of autologous conditioned serum (Orthokine) injection into the oval foramen in pain control in trigeminal neuralgia patients: a pilot study

Public title
The effect of autologous conditioned serum (Orthokine) in the treatment of trigeminal neuralgia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of idiopathic trigeminal neuralgia Complaining of severe pain refractory to oral medications

Exclusion criteria:
Bleeding disorders Drug addiction Drug sensitivity Psychopathy

Age
From **19 years** old to **70 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

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
6987598632

Approval date
2019-05-20, 1398/02/30

Ethics committee reference number
IR.TBZMED.REC.1398.170

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 intensity

Timepoint
At the beginning of the study (before the intervention) and 7, 14, 21 and 28 days after the onset of the course of treatment

Method of measurement
Verbal rating scale ranges from 0 (no pain) to 10 (maximal pain)

2

Description
Pain duration

Timepoint
At the beginning of the study (before the intervention) and 7, 14, 21 and 28 days after the onset of the course of treatment

Method of measurement
Self-declaration

3

Description
Pain daily frequency

Timepoint
At the beginning of the study (before the intervention) and 7, 14, 21 and 28 days after the onset of the course of treatment

Method of measurement
Self-declaration

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Injection of 2 milliliter autologous conditioned serum into the foramen ovale following the fluoroscopy procedure after the injection of a safe contrast agent and approved place, three times a week apart. Fifty milliliters of ' blood will be drawn from ante-cubital vein of the patients into a blood bag and be transferred to an autoclaved centrifuge tube without anticoagulants. Blood will be incubated aseptically at 37 °C for 24 hours. After incubation the tubes will be centrifuged at 3500 rpm for 10 minutes to retrieve the autologous conditioned serum.

Category
Treatment - Other

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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Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Abolghasem Jouyban

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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

Full name of responsible person
Dawood Aghamohammadi

Position
Associate professor

Latest degree
Subspecialist

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)
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