

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of superior cervical sympathetic ganglion block using radiofrequency in the treatment of adult patients with tinnitus

Protocol summary

Study aim

Determining the effect of superior cervical sympathetic ganglion block using radiofrequency in the treatment of patients with Tinnitus

Design

This clinical trial has two control and intervention groups, with parallel groups, one-blind, randomized, on 40 patients.

Settings and conduct

Patients are included in the study based on the entry and exit criteria and after obtaining written consent. They are divided into two groups. the control group, which is treated with Cinnarizine, and the intervention group, which was previously treated with Cinnarizine, but did not respond to the treatment, and will now be treated with Radiofrequency. All patients are subjected to superior cervical sympathetic ganglion block by a specialist doctor in completely sterile conditions. One week, one month, 3, 6, 12, 18 and 24 months (within two years) after the procedure, patients will be examined in person at the clinic. The person evaluating the improvement of tinnitus after treatment will not be aware of the type of treatment performed on the patient, and blinding will be done in a one-way blind. The place of the study is Bo-Ali Sina Medical Education Center, Sari.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People who are over 18 years old
Patients with Tinnitus without response to drug treatment
Patients who have been examined neurologically and do not have neurological problem
Exit criteria: People with known neurological diseases such as MS
Patient with coagulation disorders or use of anticoagulants

Intervention groups

Intervention group: Patients with Radiofrequency treatment on superior cervical sympathetic ganglion block
Control group: Patients treated with cinnarizine drug

Main outcome variables

Nausea - vomiting / bleeding in the operation area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231113060043N1**

Registration date: **2023-12-23, 1402/10/02**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-23, 1402/10/02**

Update count: **0**

Registration date

2023-12-23, 1402/10/02

Registrant information

Name

maryam daneshian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4203 5804

Email address

daneshian@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-19, 1402/08/28

Expected recruitment end date

2024-01-18, 1402/10/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Cinnarizine 10, 4, 3, Cinnarizine 10, 4, 4, Group Ganglion Block 11, 4, 1, Cinnarizine 11, 4, 2, Group Ganglion Block 11, 4, 3, Group Ganglion Block 11, 4, 4, Cinnarizine 12, 4, 1, Group Ganglion Block 12, 4, 2, Group Ganglion Block 12, 4, 3, Cinnarizine 12, 4, 4, Cinnarizine 13, 4, 1, Group Ganglion Block 13, 4, 2, Cinnarizine 13, 4, 3, Group Ganglion Block 13, 4, 4, Cinnarizine
Scientific title	Blinding (investigator's opinion)
The effect of superior cervical sympathetic ganglion block using radiofrequency in the treatment of adult patients with tinnitus	Single blinded
Public title	Blinding description
The effect of superior cervical sympathetic ganglion block using radiofrequency in the treatment of tinnitus	The person evaluating the improvement of tinnitus after treatment will not be aware of the type of treatment performed on the patient, and blinding will be done in a single blind.
Purpose	Placebo
Treatment	Not used
Inclusion/Exclusion criteria	Assignment
Inclusion criteria:	Parallel
Patients with Tinnitus without response to drug treatment Patients who have been examined neurologically and do not have neurological problem People who are over 18 years old	Other design features
Exclusion criteria:	
Taking drugs that cause tinnitus, such as: Aminoglycosides and Loop diuretics People with known neurological diseases such as MS Patients with coagulation disorders or the use of anticoagulant drugs Patients who in addition to tinnitus, have neck injuries, especially in the C2 region, and other neck problems such as cervical spinal canal stenosis. Lack of patient satisfaction and cooperation	Secondary Ids
Age	empty
From 18 years old to 65 years old	Ethics committees
Gender	1
Both	Ethics committee
Phase	Name of ethics committee
N/A	Ethics Committee of Mazandaran University of Medical Sciences
Groups that have been masked	Street address
Outcome assessor	Mazandaran University of Medical Sciences and Health Care Services Building No. 2 , Moalem Square, Sari
Sample size	City
Target sample size: 40	Sari
Randomization (investigator's opinion)	Province
Randomized	Mazandaran
Randomization description	Postal code
Patients will be included in the study based on a randomly prepared list. This list contains a series of random numbers, each number is assigned to a type of treatment and according to that treatment is done. 1, 4, 1, Group Ganglion Block 1, 4, 2, Cinnarizine 1, 4, 3, Cinnarizine 1, 4, 4, Group Ganglion Block 2, 4, 1, Group Ganglion Block 2, 4, 2, Cinnarizine 2, 4, 3, Group Ganglion Block 2, 4, 4, Cinnarizine 3, 4, 1, Cinnarizine 3, 4, 2, Group Ganglion Block 3, 4, 3, Group Ganglion Block 3, 4, 4, Cinnarizine 4, 4, 1, Group Ganglion Block 4, 4, 2, Group Ganglion Block 4, 4, 3, Cinnarizine 4, 4, 4, Cinnarizine 5, 4, 1, Cinnarizine 5, 4, 2, Cinnarizine 5, 4, 3, Group Ganglion Block 5, 4, 4, Group Ganglion Block 6, 4, 1, Cinnarizine 6, 4, 2, Group Ganglion Block 6, 4, 3, Cinnarizine 6, 4, 4, Group Ganglion Block 7, 4, 1, Group Ganglion Block 7, 4, 2, Group Ganglion Block 7, 4, 3, Cinnarizine 7, 4, 4, Cinnarizine 8, 4, 1, Cinnarizine 8, 4, 2, Group Ganglion Block 8, 4, 3, Cinnarizine 8, 4, 4, Group Ganglion Block 9, 4, 1, Cinnarizine 9, 4, 2, Group Ganglion Block 9, 4, 3, Cinnarizine 9, 4, 4, Group Ganglion Block 10, 4, 1, Group Ganglion Block 10, 4, 2,	Approval date
	2023-11-06, 1402/08/15
	Ethics committee reference number
	IR.MAZUMS.REC.1402.444
	Health conditions studied
	1
	Description of health condition studied
	Tinnitus
	ICD-10 code
	H93.19
	ICD-10 code description
	Tinnitus, unspecified ear
	Primary outcomes

1

Description

Improvement in tinnitus

Timepoint

One week, one month, 3, 6, 12, 18 and 24 months (within two years) after the procedure

Method of measurement

Patients will rate the degree of improvement of tinnitus using a scoring questionnaire from 0 to 10

Secondary outcomes

1

Description

Nausea - vomiting

Timepoint

Immediately after the operation - 3 hours later 6, 12 and 24 hours after the operation - one week later

Method of measurement

Examination and expression by the patient

2

Description

bleeding in the operation area

Timepoint

during the operation, 1hour , 6, 12, 24 hours after the operation

Method of measurement

Examination and observation by a doctor

Intervention groups

1

Description

Intervention group: There are patients who, after checking the sensory and motor nerves, in order to prevent nerve damage, and after choosing the correct location, which is basically in the roots of c1, c2, c3, They are treated with a block of the superior sympathetic ganglion of the neck using a radiofrequency pulse

Category

Treatment - Surgery

2

Description

Control group: There are patients who are treated with the drug Cinnarizine 25 twice a day. That is, with an average dose of 50 mg daily, people will be treated with medicine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bo Ali Sina Hospital, Sari

Full name of responsible person

Maryam Daneshian

Street address

Bo Ali Sina Medical Education Center, Pasdaran Blvd., Mazandaran,

City

Sari

Province

Mazandaran

Postal code

4815838477

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Email

daneshian@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Alia Zamani Kiasari

Street address

Mazandaran University of Medical Sciences, Serah Joibar, Imam Square, Sari

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Ali Fahimi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Maryam Daneshian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Full name of responsible person

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Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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