Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of Osvix on tinnitus and Headache in patient with transverse venous sinus stenosis or hypoplasia

Protocol summary

Study aim
Determining the effect of Osvix drug on tinnitus and headache in patients with stenosis or hypoplasia of the transverse venous sinus.

Design
42 available patients were included in the study and were treated with 75 mg of Osvix daily for one month, and before and after the intervention, they were evaluated for the severity of disability caused by headache and tinnitus.

Settings and conduct
42 available patients referred to the neurology clinic of Imam Reza Hospital with symptoms of tinnitus and headache, diagnosed by a neurologist in vascular imaging as having stenosis or hypoplasia of the transverse venous sinus, were included in the study. They are given 75 mg of Osvix daily, and before and after the intervention, they are evaluated in terms of the severity of disability caused by headache and tinnitus by a questionnaire.

Participants/Inclusion and exclusion criteria
Age between 18 and 68 years Having tinnitus and headache, and unilateral or bilateral stenosis or hypoplasia in the transverse venous sinus evident in MRV The absence of known neurological diseases leading to tinnitus, Pregnancy and breastfeeding

Intervention groups
42 patients were included in the study and were treated for one month with 75 mg of Osix daily.

Main outcome variables
Reducing the sensation of Tinnitus and headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220715055474N1**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **retrospective**

Last update: **2023-08-12, 1402/05/21**
Update count: **0**

Registration date
2023-08-12, 1402/05/21

Registrant information

Name
Ali Mirzaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4453 4450

Email address
amteh76@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-15, 1402/02/25

Expected recruitment end date
2023-07-23, 1402/05/01

Actual recruitment start date
2023-05-15, 1402/02/25

Actual recruitment end date
2023-07-23, 1402/05/01

Trial completion date
2023-07-23, 1402/05/01

Scientific title
Evaluation of the effect of Osvix on tinnitus and Headache in patient with transverse venous sinus stenosis or hypoplasia

Public title
Evaluation of the effect of Osvix on tinnitus and Headache in patient with transverse venous sinus

stenosis or hypoplasia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Tinnitus and headache with venous sinus stenosis or hypoplasia

Exclusion criteria:

Known neurological disease Pregnancy or breastfeeding Patient dissatisfaction

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **42**

Actual sample size reached: **42**

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

Research Ethics Committees AJA University of Medical Sciences

Street address

West Fatemi Street, Shahid Etemad Zadeh Street, Army University of Medical Sciences

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Postal code

1411718541

Approval date

2023-05-15, 1402/02/25

Ethics committee reference number

IR.AJAUMS.REC.1402.033

Health conditions studied

1

Description of health condition studied

Tinnitus and headache and transverse venous sinus stenosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of disability caused by tinnitus and headache by Tinnitus handicap inventory and Headache disability index

Timepoint

At the beginning of the study and thirty days after the intervention

Method of measurement

Tinnitus handicap inventory and Headache disability index

Secondary outcomes

1

Description

Tinnitus and headache severity score measured by Tinnitus handicap inventory and Headache disability index questionnaires

Timepoint

30 days after the intervention

Method of measurement

Tinnitus and headache severity score measured by Tinnitus handicap inventory and Headache disability index questionnaires

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Ali Mirzaei

Street address

Fatemi West Street, Shahid Etemadzadeh Street, Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Vice President of Research and Technology
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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
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Ali Mirzaei
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Student
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Other areas of specialty/work
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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