

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of Nuerotec on Improving of Tinnitus signs and symptoms

Protocol summary

Summary

In this double-blind randomized clinical trial the therapeutic effect of Neurotec on improvement of Tinnitus was investigated. Hundred patients with chief complaint of Tinnitus were examined and diagnosed by a single otolaryngologist and were randomly allocated to two intervention and control group using random number table. Patients with Informed consent, Tinnitus for at least 6 months and Age over 19 were included in the trial. Patients with Pregnancy, Age over 75 and under 19, Chronic or Acute neurologic disease, Psychologic disease, Previous surgery on the affected ear, Pulsatile Tinnitus, Epilepsy, Multiple sclerosis, History of sever trauma to head and neck and History of treatment 1 month prior to intervention were excluded from the trial. Patients in intervention group underwent treatment with Neurotec 100 mg (twice daily) and patients in control group underwent treatment with placebo in the same manner. All the patients received the main treatment which is education and reassurance. All patients in both groups underwent Pure Tone Audiometry (PTA) and filled Tinnitus Handicap Inventory (THI) before, one month and 3 months after intervention and the results were compared together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042817413N23**

Registration date: **2017-05-29, 1396/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-29, 1396/03/08

Registrant information

Name

Hamidreza Karimi-Sari

Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Baqiyatallah University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Nuerotec on Improving of Tinnitus signs and symptoms

Public title

Therapeutic effects of Neurotec on Improving Tinnitus in patients attending to Baqiyatallah Clinic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1- Informed consent 2- Tinnitus for at least 6 months 3- Age over 19 Exclusion criteria: 1- Pregnancy 2-Age over 75 and under 19 3-Chronic or Acute neurologic disease 4-Psychologic disease 5- Previous surgery on the affected ear 6-Pulsatile Tinnitus

7-Epilepsy 8-Multiple sclerosis 9- History of sever trauma to head and neck 10- History of treatment 1 month prior to intervention

Age

From **19 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Nosrati ave., South Sheykh Bahaei, Mollasadra st., Vanaq sq., Tehran

City

Tehran

Postal code

Approval date

2016-08-01, 1395/05/11

Ethics committee reference number

IR.BMSU.REC.1395.176

Health conditions studied

1

Description of health condition studied

Tinnitus

ICD-10 code

H93.1

ICD-10 code description

Tinnitus

Primary outcomes

1

Description

Hearing Threshold

Timepoint

Before, one month and three months after interventin

Method of measurement

Pure Tone Audiometry

2

Description

Quality of Life

Timepoint

Before, one month and three months after interventin

Method of measurement

Tinnitus Handicap Inventory

Secondary outcomes

1

Description

Drug Complications

Timepoint

During study

Method of measurement

Patients' complaint

Intervention groups

1

Description

Intervention group underwent treatment with Neurotec capsule 100 mg twice daily for 3 months

Category

Treatment - Drugs

2

Description

Control group patients underwent treatment with placebo twice daily for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Mohammad Hossein Khosravi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Baqiyatallah University of Medical Sciences

Full name of responsible person

Morteza Izadi

Street address

Baqiyatallah University of Medical Sciences, Nosrati Alley, Sheykh Bahaei st., Mollasadra st., Vanaq sq., Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Baqiyatallah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Student Research Committee, Baqiyatallah University of Medical Sciences, Tehran, Iran

Full name of responsible person

Mohammad Hossein Khosravi

Position

Secretary-General

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Department of Otorhinolaryngology, Head and Neck Surgery, Faculty of Medicine, Baqiyatallah University

Full name of responsible person

Masoumeh Saeedi

Position

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

