Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Otolaryngologist

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Person responsible for updating data

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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

Data Dictionary	*empty*