

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8126 4354

##### Email address

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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

**Other areas of specialty/work****Street address**

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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

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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*

