

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluation of Carbamazepine and Oxcarbazepine effect on Tinnitus in patients referred to Amir Almomentin Hospital rasht-iran.

#### Protocol summary

##### Summary

Tinnitus is a common disorder in general population and affect many age groups. Permanent tinnitus is seen in 6-30% of general population, and 25% of these cases ( about 4% general population) tinnitus is very severe that leads to physical and psychological disorders and hampers their quality of life. Recently, the researchers in this field, believe that tinnitus is a seizure type activity in the cortical and sub cortical areas of the brain that leads to aberrant acoustic perception. Therefore anti epileptic agents have been suggested for decrease of tinnitus intensity and relief of the patients from annoying tinnitus. After initial examination the tinnitus subjects by otolaryngologist, the patients will be recruited into the study. Audiometry and tinnitus tests will be performed and then, the patients explain their tinnitus intensity by use of VAS. Also the tinnitus severity index (TSI) questionnaire will be completed for them. After explaining the process of the trial, written informed consent will be obtained from participants. Then they will be divided into three groups randomly: for the first group; carbamazepine, for the second group; oxcarbazepine; and for the third group placebo will be administered for 3 months (12 weeks). At the end of 8th and 12th weeks of study tinnitus intensity will be evaluate by VSA criteria and tinnitus quality and patient quality of life will be re-evaluated using TSI questionnaire. Then the results of intervention in three groups will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903061138N2**

Registration date: **2010-05-27, 1389/03/06**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2010-05-27, 1389/03/06

##### Registrant information

###### Name

Fataneh Bakhshi

###### Name of organization / entity

Guilan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 1223 8307

###### Email address

entrc@gums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Guilan University of Medical sciences, Vice chancellor for Research

##### Expected recruitment start date

2010-08-21, 1389/05/30

##### Expected recruitment end date

2011-04-21, 1390/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Carbamazepine and Oxcarbazepine effect on Tinnitus in patients referred to Amir Almomentin Hospital rasht-iran.

##### Public title

Effect of Carbamazepine and Oxcarbazepine on Tinnitus

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: 1-tinnitus history more than 6 months; 2- The patients 21-65 years with nonpulsatile tinnitus. Exclusion criteria: 1-pulsatile tinnitus 2-mineare's disease 3-vestibular neurinoma 4-otosclerosis 5-the patients use of hearing-aid 6-pregnancy 7- patients with psychologic disorders need to treatment 8-the nontolerance minimal dose of carbamazepine and oxcarbazepine or hypersensitivity to these drugs 9-recent treatment with anti convulsion drugs 10-OCP consumptions and the drugs interaction with carbamazepine but are necessary to patients 10-patients with severe heart disease(CHF,IHD) 11- appearance severe drug hypersensitivity reaction during of treatment

### **Age**

From **20 years** old to **65 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **57**

### **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**

Guilan University of Medical Sciences

##### **Street address**

Amiralmomenin Hospital

##### **City**

Rasht

##### **Postal code**

41439

#### **Approval date**

2010-05-22, 1389/03/01

#### **Ethics committee reference number**

1023/132/پ

## **Health conditions studied**

### 1

#### **Description of health condition studied**

nonpulsatile tinnitus

#### **ICD-10 code**

H83

#### **ICD-10 code description**

Other diseases of inner ear

## **Primary outcomes**

### 1

#### **Description**

Tinnitus severity

#### **Timepoint**

The beginning of treatment and ending of 8th and 12th week

#### **Method of measurement**

VAS & TSI

### 2

#### **Description**

Quality of Life

#### **Timepoint**

The beginning of treatment and ending of 8th and 12th week

#### **Method of measurement**

TSI

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Group A(carbamazepine): week 1 = tab 200 mg/daily  
week 2 -week 12= tab 600 mg/daily (300 mg/ BD)

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Group b( oxcarbazepine ): week 1= 300 mg/daily then  
week2- week12 = 900 mg/ daily (450 mg BID)

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Group C: intervention with placebo

#### **Category**

Placebo

## **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Rasht Amiralmomenin Hospital

**Full name of responsible person**

Dr Houshang Gerami

**Street address**

Amiralmomenin Hospital, 17 Shahrivar Ave.

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+98 13 1222 5242

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**Email**

gerami@gums.ac.ir

**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Vice Chancellor for research

**Street address**

Amiralmomenin Hospital, Namjou street, Rasht, Guilan, Iran

**City**

Rasht

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Guilan 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**

Guilan University of Medical Sciences

**Full name of responsible person**

Dr Houshang Gerami

**Position**

Assistant professor

**Other areas of specialty/work**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Dr Houshang Gerami

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

Amiralmomenin hospital

**City**

Rasht

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+98 13 1222 5242

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**Email**

gerami@gums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

## 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*