

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Effect of acupuncture on tinnitus severity in non pulsatile tinnitus patients

#### Protocol summary

##### Summary

Acupuncture is one of probable treatment for tinnitus. The goal of this study is searching for effect of acupuncture on non pulsatile tinnitus. This study is randomized clinical trial and the patients randomly are divided to two groups of case and control. 88 Patient between 20 to 65 that are diagnosed in primary examinations are divided to two groups of case and control. Case patients are treated in 15 sessions for three times a week in acupuncture points and by an acupuncture specialist. As the same the control group are treated but in the points that do not have effect on tinnitus. Patients fill the severity tinnitus questionnaire in the end of 5, 10, 15 session and 3 weeks after treatment. The patients are followed until the end of fifteenth session and the the severity of tinnitus are compared in two group. Patients are considered through the treatment for acupuncture complications.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201404191138N11**

Registration date: **2015-02-06, 1393/11/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-02-06, 1393/11/17

##### Registrant information

###### Name

Fataneh Bakhshi

###### Name of organization / entity

Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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entrc@gums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Guilan University of Medical Science, Vice Chancellor for Research

###### Expected recruitment start date

2015-08-22, 1394/05/31

###### Expected recruitment end date

2016-08-21, 1395/05/31

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effect of acupuncture on tinnitus severity in non pulsatile tinnitus patients

###### Public title

Effect of acupuncture on non pulsatile tinnitus

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: patients 20-65; non pulsatile tinnitus

Exclusion criteria: Pulsatile tinnitus; patients with meniere disease, vestibular neurinoma, otosclerosis; pregnant women; patients younger than 20; patients older than 65

###### Age

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

###### Gender

Both

###### Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 88

## 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

Tehran avenue

##### City

Rasht

##### Postal code

#### Approval date

2014-06-02, 1393/03/12

#### Ethics committee reference number

1930111206

## Health conditions studied

### 1

#### Description of health condition studied

Tinnitus

#### ICD-10 code

H93.1

#### ICD-10 code description

Other abnormal auditory perceptions Auditory recruitment Diplacusis Hyperacusis Temporary auditory threshold shift Excl.: auditory hallucinations (R44.0)  
H93.3 Disorders of acoustic nerve Disorder of 8th cranial nerve H93.8 Other specified disorders of ea

## Primary outcomes

### 1

#### Description

Tinnitus severity

#### Timepoint

On days 5,10,15 and three week after acupuncture

#### Method of measurement

VAS ,TSI

## Secondary outcomes

### 1

#### Description

Infection

#### Timepoint

In Acupuncture Period

#### Method of measurement

Physician

### 2

#### Description

CNS Disturbance

#### Timepoint

In Acupuncture Period

#### Method of measurement

Physician

### 3

#### Description

Pneumothorax

#### Timepoint

In Acupuncture Period

#### Method of measurement

Physician

### 4

#### Description

Cardiac Disease

#### Timepoint

In Acupuncture Period

#### Method of measurement

Physician

## Intervention groups

### 1

#### Description

Patients randomly are divided to two groups of case and control. Case patients are treated in 15 sessions for three times a week in acupuncture points and by an acupuncture specialist. Patients fill the severity tinnitus questionnaire in the end of 5 ,10 ,15 session and 3 weeks after treatment.

#### Category

Treatment - Other

### 2

#### Description

Control patients are treated in 15 sessions for three times a week by an acupuncture specialist in the points that do not have effect on tinnitus. Patients fill the severity tinnitus questionnaire in the end of 5 ,10 ,15 session and 3 weeks after treatment

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Amiralmomenin Hospital

**Full name of responsible person****Street address****City**

Rasht

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Guilan University of Medical Sciences, Vice Chancellor  
For Research**Full name of responsible person**

Susan komae

**Street address**

Namjou st, Rasht

**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, Vice Chancellor For  
Research**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 Shademan Nemati

**Position**

Asistant Professor

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

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Guilan Univercity Of Medical Sciences

**Full name of responsible person**

Dr Shademan Nemati

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**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*