

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of acupuncture on the inner ear originated tinnitus

Protocol summary

Summary

Evaluation of effect of acupuncture on the inner ear originated tinnitus is the purpose of this study. This prospective clinical trial study has been done in Al-zahra and Kashani hospitals in Isfahan, Iran in 2010-2011. Method of patient selection was simple. 54 patients of this study were divided into two groups of case and control. HADs questionnaire for anxiety and depression, tinnitus severity index questionnaire and also tinnitus loudness scale were completed by patients. Two latter questionnaires were completed again after 5th and 10th session of Acupuncture treatment. The number of patients in each group was 27. Case group was treated with effective acupuncture but control group was treated ineffectively, as similar to usual acupuncture method but by fake needles. independent T test was used to compare the mean of tinnitus severity index and loudness score between two groups. Repeated measures ANOVA test was used to compare the mean of tinnitus severity index and loudness for different assessments in either group. After 5th and 10th sessions of treatment, the mean of tinnitus severity index and mean of tinnitus loudness evaluated in both group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106036699N1**

Registration date: **2011-06-27, 1390/04/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-27, 1390/04/06

Registrant information

Name

Mehrdad Rogha

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3664 0352

Email address

rogha@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan university of medical sciences

Expected recruitment start date

2010-06-05, 1389/03/15

Expected recruitment end date

2011-04-04, 1390/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of acupuncture on the inner ear originated tinnitus

Public title

Effect of acupuncture on the inner ear originated tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: chronic tinnitus; Tinnitus with out any certain structural cause, Exclusion criteria: Patient request; patients with poor compliance.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 54

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan university of medical sciences

Street address

Hezarjarib street

City

Isfahan

Postal code**Approval date**

2010-06-06, 1389/03/16

Ethics committee reference number

389104

Health conditions studied**1****Description of health condition studied**

Tinnitus

ICD-10 code

H83.9

ICD-10 code description

Disease of inner ear, unspecified

Primary outcomes**1****Description**

Tinnitus loudness

Timepoint

Before treatment, After 5 and 10 session of treatment

Method of measurement

questionnaire

2**Description**

Tinnitus severity

Timepoint

Before treatment, After 5 and 10 session of treatment

Method of measurement

questionnaire

Secondary outcomes**1****Description**

Anxiety

Timepoint

Before treatment

Method of measurement

questionnaire

2**Description**

Depression

Timepoint

Before treatment

Method of measurement

questionnaire

Intervention groups**1****Description**

Case group was treated by acupuncture for 10 session effectively by true acupuncture needle

Category

Treatment - Other

2**Description**

Control group was treated ineffectively, as similar to usual acupuncture method but by fake needles

Category

Other

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

Kashani hospital

Full name of responsible person

Mehran Rezvani, Assistant professor

Street address

Kashai street, Kashani hospital

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan university of medical sciences

Full name of responsible person

Isfahan university of medical sciences

Street address

Hezarjarib street

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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

Isfahan university of medical sciences

Full name of responsible person

Mehran Rezvani

Position

Assistant professor

Other areas of specialty/work

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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