

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of the effect intra tympanic methylprednisolon injection and intra tympanic gentamicin injection in control vertigo in patients with unilateral meniere's disease.

Protocol summary

Summary

This study aims to compare the effect of intra tympanic methylprednisolon injection versus intra tympanic gentamicin injection in vertigo control. Inclusion criteria: Patients with unilateral meniere's disease; Exclusion criteria: patients with bilateral meniere's disease; patients whose involved ear is the only hearing ear; not suffering from central nervous system disease; patients who do not let to inject. The experimental group contains 20 patients, Patients are divided into two groups and then 27.6 mg of gentamicin is injected to one group and 62.5 mg metylprednisolon is injected to the other group for three week. Finally the groups vertigo, tinnitus and hearing loss are compared 3 to 6 month after the last injection by questionnaires and radiometry.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041021582N1**

Registration date: **2015-05-31, 1394/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-31, 1394/03/10

Registrant information

Name

Armin Arad

Name of organization / entity

Ahvaz university of medical sciencesy

Country

Iran (Islamic Republic of)

Phone

+98 613367543

Email address

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Recruitment status

Recruitment complete

Funding source

Ahvaz university of Medical Sciences

Expected recruitment start date

2014-11-29, 1393/09/08

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect intra tympanic methylprednisolon injection and intra tympanic gentamicin injection in control vertigo in patients with unilateral meniere's disease.

Public title

The effect of gentamicin and methylprednisolon on vertigo.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with unilateral meniere's disease; Exclusion criteria: patients with bilateral meniere's disease; patients whose involved ear is the only hearing ear; not suffering from central nervous system disease; dissatisfaction

Age

No age limit

Gender

Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 20

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of ahvaz university of Medical Sciences

Street address

Ahvaz University of Medical Sciences, Golestan street

City

Ahvaz

Postal code

15794_61357

Approval date

2014-11-29, 1393/09/08

Ethics committee reference number

ajums.rec.1392.292

Health conditions studied

1

Description of health condition studied

Meniere,s disease

ICD-10 code

h81.0

ICD-10 code description

Meniere,s disease

Primary outcomes

1

Description

Vertigo

Timepoint

before treatment and 3 months later

Method of measurement

Questennaire

Secondary outcomes

1

Description

Tinnitus

Timepoint

before treatment and 3 month later

Method of measurement

Questennaire

2

Description

hearing loss

Timepoint

before treatment and 3 month later

Method of measurement

audiometry

Intervention groups

1

Description

intervention group 1- gentamicin with dose 27.6 mg once via intra tympanic injection

Category

Treatment - Drugs

2

Description

intervention group 2- methyl perednosolone with dose 62.5 mg weekly intra tympanic injection in three times

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Ahvaz

Full name of responsible person

Armin arad

Street address

Azadegan street, Imam Khomeini Hospital of Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy for research of Avaz University of Medical Sciences

Full name of responsible person

Dr. Nader Saki

Street address

Golestan street, Ahvaz University of Medical Sciences

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy for research of Avaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Armin Arad

Position

Resident of ENT

Other areas of specialty/work

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Web page address

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