

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

study on effectiveness of methyl prednisolon intratemporic injection in compared to dexametason indoepatic hydrops and tinnitus cure in definite menier patients with using of ECOG test

Protocol summary

Summary

Objective: study on effectiveness of methyl prednisolon intratemporic injection in compared to dexametason indoepatic hydrops and tinnitus cure in definite menier patients Design: clinical trial Setting and conduct: Definite Meniere's disease Amir Alam hospital for three months did not respond to routine treatment were enrolled and randomly divided into two groups. In a intratympanic injections of methyl prednisolone (40mg / 1ml) and the other group intratympanic injection of dexamethasone (8 mg / 2ml) done. Inclusion criteria: Patients between 18 and 80 years, did not respond to treatment salt restriction, diuretics and betahistine for three months Exclusion criteria: Disease of neuromuscular system, diseases of the spinal cord and CNS disease of the middle ear, otitis media, conductive hearing loss, taking ototoxic, drug addiction, patients with a history of middle ear surgery, surgical intervention in the inner ear, patients by menier bilateral and perforation of the tympanic membrane and absence of systemic corticosteroid treatment Intervention: 41 patients with definite Meniere clinic under local anesthesia in each group and prednisone or dexamethasone intratympanic injection for intratympanic. Three injections can be done within a week. Two to 4 weeks after injection, electrocochleography test will be performed. No control group Main outcome measures (variables): Improvement in vertigo

General information

Acronym

تست الکتروکوکلوگرافی

IRCT registration information

IRCT registration number: **IRCT2015102912691N3**
Registration date: **2016-01-19, 1394/10/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-19, 1394/10/29

Registrant information

Name

Nasrin Yazdani

Name of organization / entity

Tehran university of Medical Sciences, Amir Alam Hospital

Country

Iran (Islamic Republic of)

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+98 21 6676 0269

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

study on effectiveness of methyl prednisolon

intratemporal injection in compared to dexametason
indoenphatic hydrops and tinnitus cure in definite menier
pations with using of ECOG test

Public title

study on effectiveness of methyl prednisolon
intratemporal injection in compared to dexametason
indoenphatic hydrops and tinnitus cure in definite menier
pations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients between 18 and 80 years, did
not respond to treatment salt restriction, diuretics and
betahistine for three months Exclusion criteria: Disease
of neuromuscular system, diseases of the spinal cord and
CNS disease of the middle ear, otitis media, conductive
hearing loss, taking ototoxic, drug addiction, patients
with a history of middle ear surgery, surgical intervention
in the inner ear, patients by menier bilateral and
perforation of the tympanic membrane and absence of
systemic corticosteroid treatment

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Tehran University of Medical
Sciences

Street address

Ghods Street, Keshavarz Boulevard

City

Tehran

Postal code

1417653761

Approval date

2015-06-25, 1394/04/04

Ethics committee reference number

IR.TUMS.REC.343

Health conditions studied

1

Description of health condition studied

Meniere

ICD-10 code

H81.0

ICD-10 code description

Ménière disease

Primary outcomes

1

Description

Vertigo

Timepoint

Arrival, 2 to 4 weeks, every 6 weeks for 6 to 12 months

Method of measurement

Audiometry Test and questionnaire

Secondary outcomes

1

Description

hearing

Timepoint

Arrival, 2 to 4 weeks, every 6 weeks for 6 to 12 months

Method of measurement

Audiometry Test

2

Description

Tinnitus

Timepoint

Arrival, 2 to 4 weeks, every 6 weeks for 6 to 12 months

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group 1: 41 patients with definite Meniere
intratympanic methyl prednisolone injections at the clinic
undergoing local anesthesia for intratympanic.

Category

Treatment - Drugs

2

Description

Intervention group 2: 41 patients with definite Meniere intratympanic dexamethasone injections at the clinic undergoing local anesthesia for intratympanic.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

AmirAlam Hospital

Full name of responsible person

Dr Nasrin Yazdani

Street address

Amir Alam Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellorfor Research, Tehran University of Medical Sciences

Full name of responsible person

Dr Masoud Younesian

Street address

Central Organization of Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulevard

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Tehran

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellorfor Research, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

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Position

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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