

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of intra-tympanic dexamethasone with alterations of electrocochleography in meniere's patients.

Protocol summary

Summary

To assess the effectiveness of intra-tympanic dexamethasone on the frequency and severity of attacks of vertigo, on chronic symptoms such as tinnitus, imbalance and hearing loss, and on the progression of these symptoms in patients with definite meniere's disease or syndrome, as defined by the AAO-HNS Committee. We also use electrocochleography (ECOG) for evaluation of hydrops before and after of injection. Materials and Methods :A prospective cohort study including 25 adult patients of a tertiary referral ENT clinic whom definite , unilateral meniere's patients and non responsive to medical treatment was selected. also they had no prior ear surgery or other medical comorbidity. Baseline ECOG obtained , treatment with 4mg (IT-Dex) , (3 doses totally &with a week interval) was carried out. We recorded Post treatment ECOG, one month after 3rd (IT-Dex) injection , and evaluated clinical sign 6 to 12 months after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050112691N2**
Registration date: **2014-12-08, 1393/09/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-08, 1393/09/17

Registrant information

Name

Nasrin Yazdani

Name of organization / entity

Tehran university of Medical Sciences, Amir Alam

Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 6676 0269

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2013-02-28, 1391/12/10

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of intra-tympanic dexamethasone with alterations of electrocochleography in meniere's patients.

Public title

Evaluation of intra-tympanic dexamethasone in meniere disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Definite meniere ; Age beyond 18 years; NOresponse to medical mangment
Exclusion criteria: Musculoskeletal disease ; Spinal cord disease; Middle ear disease ; Addiction ;Usage of ototoxic drugs

Age

No age limit

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **23**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Scicence

Street address
Poursinastreet ; 16 azar street ; Keshavarz blvd

City
Tehran

Postal code

Approval date
2014-09-13, 1393/06/22

Ethics committee reference number
23349

Health conditions studied

1

Description of health condition studied
Meniere disease

ICD-10 code
H81.0

ICD-10 code description
Ménière disease

Primary outcomes

1

Description
Vertigo

Timepoint
1 ; 3 and 6 months

Method of measurement
In respect to standardized questionnaire

Secondary outcomes

1

Description
tinnitus ;hearing level

Timepoint
1 ; 3 and 6 months

Method of measurement
Audiometry / respect to questionnaire

Intervention groups

1

Description
4 mg intratympanic dexamethasone injection 3 doses toally with 1 week interval.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir-Alam hospital

Full name of responsible person
Reza. Gharibi.MD

Street address
Northern saadi street, Darwaze Dowlat , Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Science

Full name of responsible person
Mrs.Mokhtari

Street address
Poursina street ; Keshavarz blvd ; Tehran

City
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Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Science

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***Phone**

+98 21 6676 0245

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Amir Alam hospital

Full name of responsible person

Reza Gharibi

Position

Otorhinolaryngology resident

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Tehran

Postal code**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*