

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Therapeutic effect of intratympanic dexamethasone and hyaluronic acid combination on Meniere's disease patients

Protocol summary

Study aim

Evaluating the therapeutic effect of intratympanic dexamethasone and hyaluronic acid combination on Meniere's disease

Design

Clinical trial, without a control group, without blinding

Settings and conduct

Sampling in this study is done in Kashani and Alzahra hospitals in Isfahan. The patients with Meniere's disease are selected based on the American committee of otolaryngology-Head & neck surgery guideline. The intervention group receives two intratympanic injections of 0.3 ml dexamethasone and 0.2 ml hyaluronic acid as a mixture and the interval between two injections is one month. Patients are examined for hearing impairment, vertigo and tinnitus before and two weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Meniere's disease and resistant to other treatments such as lifestyle modifications, vasodilators or diuretics during the last 6 months. Exclusion criteria: Nothing.

Intervention groups

The intervention group receives two intratympanic injections of 0.3 ml dexamethasone (manufacture by Abidi company) and 0.2 ml hyaluronic acid (Hyalgan manufacture by Fidia Pharma USA) as a mixture and the interval between two injections is one month.

Main outcome variables

Hearing impairment, vertigo, tinnitus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N25**

Registration date: **2018-12-07, 1397/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-07, 1397/09/16**

Update count: **0**

Registration date

2018-12-07, 1397/09/16

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3629 1510

Email address

mehrabi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-01, 1396/10/11

Expected recruitment end date

2018-12-30, 1397/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effect of intratympanic dexamethasone and hyaluronic acid combination on Meniere's disease patients

Public title

Effect of dexamethasone and hyaluronic acid combination on Meniere's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Meniere's disease Patients resistant to other treatments such as lifestyle modifications, vasodilators or diuretics during the last 6 months

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 25

Randomization (investigator's opinion)

Not randomized

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-08-01, 1396/05/10

Ethics committee reference number

IR.MUI.REC.1396.30455

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

hearing impairment

Timepoint

Before the intervention and 2 weeks after the treatment

Method of measurement

Speech discrimination score

2

Description

Vertigo

Timepoint

Before the intervention and 2 weeks after the treatment

Method of measurement

Dizziness Handicap Inventory

3

Description

Tinnitus

Timepoint

Before the intervention and 2 weeks after the treatment

Method of measurement

Tinnitus Handicap Inventory

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: Receives two intratympanic injections of 0.3 ml dexamethasone (manufacture by Abidi company) and 0.2 ml hyaluronic acid (Hyalgan manufacture by Fidia Pharma USA) as a mixture and the interval between two injections is one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Leila Assadpour

Street address

Kashani Hospital, Kashani Street, Isfahan, Iran

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kashani@mui.ac.ir
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2

Recruitment center

Name of recruitment center
Alzahra hospital
Full name of responsible person
Leila Assadpour
Street address
Alzahra Hospital, Sofe street, Isfahan, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo Javanmard
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Isfahan University of Medical Sciences, Hezar Jerib Street
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Phone
+98 31 3668 7079
Email
sh_haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Leila Assadpour
Position
Non-faculty specialist
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only the results of the whole data are made available to the public

When the data will become available and for how long

Starting 3 months after publication

To whom data/document is available

Information is provided to Isfahan University of Medical Sciences

Under which criteria data/document could be used

The use of data is merely intended to introduce the study and examine how the parameters are measured

From where data/document is obtainable

Dr. Leila Assadpour (Project manager) Address: Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan, Iran Phone: 00983136688597 Mobile: 00989171074662 Email: leilaasadpour35@gmail.com

What processes are involved for a request to access data/document

1. No use these data in another study 2. Member of the Faculty of Medicine of Isfahan University of Medical Sciences 3. No data access to someone else

Comments