

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation the effectiveness of treatment with enoxaparin as adjunctive therapy in the treatment of patients with idiopathic retention sensorineural hearing loss

Protocol summary

Study aim

Evaluation of the effectiveness of treatment with enoxaparin as adjunctive therapy in the treatment of patients with idiopathic retention sensorineural hearing loss

Design

Randomized clinical trial using closed envelope with control group, with parallel groups, no blinding, phase 2-3 on 60 patients

Settings and conduct

This clinical trial will be performed on 60 ISSNHL patients referred to Ghaem Hospital in Mashhad. Eligible patients are divided into control and intervention groups after obtaining consent. In the control group, oral prednisolone, dexamethasone and aspirin will be received, in the intervention group, oral prednisolone and dexamethasone in total 10 times daily, plus enoxaparin twice daily will be given for 10 days, while the patients will be checked for hearing before and at the end of the 10-day treatment period.

Participants/Inclusion and exclusion criteria

Sudden idiopathic sensorineural hearing loss (ISSNHL) is rapidly progressive with no known cause for more than 72 hours without a history of ear disease and underlying diseases such as diabetes mellitus.

Intervention groups

In the control group, 30 patients with sudden sensorineural hearing loss will receive oral prednisolone (1 mg / kg), dexamethasone (5 mg / ml), and aspirin 80 mg daily for a total of 10 times. In the intervention group, oral prednisolone (1 mg / kg) and dexamethasone (5 mg / ml) in total 10 times daily and in addition, enoxaparin at a dose of 1 mg / kg will be injected subcutaneously twice daily for 10 days.

Main outcome variables

Average hearing threshold

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211010052721N2**

Registration date: **2022-06-27, 1401/04/06**

Registration timing: **prospective**

Last update: **2022-06-27, 1401/04/06**

Update count: **0**

Registration date

2022-06-27, 1401/04/06

Registrant information

Name

Navid nourizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 2081

Email address

nourizadehn@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-21, 1401/04/30

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of treatment with enoxaparin as adjunctive therapy in the treatment of patients with idiopathic retention sensorineural hearing loss

Public title

The effect of enoxaparin on sudden sensorineural deafness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Conscious consent to participate in the study Patients with sudden sensorineural hearing loss that progresses rapidly and no known cause is found for more than 72 hours

Exclusion criteria:

History of ear diseases Patients with contraindications to treatment with systemic corticosteroids or anticoagulants such as diabetes mellitus History of intermittent hearing loss Pregnancy Breastfeeding

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups

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

کمیته اخلاق دانشگاه علوم پزشکی مشهد

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Central Building of Mashhad University of Medical

Sciences (Ghoreishi), Daneshgah 16, Daneshgah Street

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Razavi Khorasan

Postal code

9117699199

Approval date

2022-05-10, 1401/02/20

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.106

Health conditions studied

1

Description of health condition studied

Sudden sensorineural hearing loss

ICD-10 code

H90.3

ICD-10 code description

Sensorineural hearing loss, bilateral

Primary outcomes

1

Description

Average hearing threshold

Timepoint

Before the intervention and 10 days after starting taking enoxaparin

Method of measurement

Audiometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, oral prednisolone (1 mg / kg) for 10 days and dexamethasone in the ear (5 mg / ml) for a total of 10 times daily plus, 1 mg / kg subcutaneously enoxaparin (enoxaparin sodium ampoule) 6000 units) will be injected twice a day for 10 days.

Category

Treatment - Drugs

2

Description

Control group: In this group, oral prednisolone (1 mg / kg) will be administered for 10 days and dexamethasone in the ear at a dose (5 mg / ml) will be given daily and a total of 10 times. Also, aspirin 80 mg daily will be prescribed.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

بیمارستان قائم

Full name of responsible person

نوید نوری زاده

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Navid Nourizadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available