

# 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

##### Street address

Central Building of Mashhad University of Medical

Sciences (Ghoreishi), Daneshgah 16, Daneshgah Street

## City

Mashhad

## Province

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 centers**1**Recruitment center****Name of recruitment center**

بیمارستان قائم

**Full name of responsible person**

نوید نوری زاده

**Street address**

Ghaem Hospital, Ahmad Abad AVE

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nourizadehn@mums.ac.ir

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Central Building of Mashhad University of Medical Sciences (Ghoreishi), Daneshgah 16, Daneshgah street

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ramresearch@mums.ac.ir

**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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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Subspecialist

**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**

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