

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison and evaluation of the effect of rivaroxaban in the complementary treatment of sudden sensorineural hearing loss

#### Protocol summary

##### Study aim

Evaluation and comparison of the effect of rivaroxaban on pure tone audiometry and word recognition score in treatment of sudden sensorineural hearing loss

##### Design

Clinical trial with control group, with parallel groups, double-blind, phase 2 on 34 patients

##### Settings and conduct

This study will be performed in 1399 in Kashani Educational-Medical Center of Isfahan. Researchers and patients are unaware of the type of drug used.

##### Participants/Inclusion and exclusion criteria

Patients over 18 years of age with sudden hearing loss without a history of hearing problems or blood coagulation are included in the study.

##### Intervention groups

Patients in both groups treated with prednisolone 1 mg / kg daily for the first 10 days of illness and intratympanic injection of dexamethasone 5 mg / ml daily for a total of up to 5 days . If patients have a partial response to corticosteroids after 10 days (based on audiometric tests), treatment with prednisolone tablets should be continued for another 10 days until further improvement is found based on audiometric tests. In the first group, patients receive 10 mg of rivaroxaban tablets daily for 10 days in addition to corticosteroid therapy, while in the second group, patients do not receive any medication other than corticosteroid therapy.

##### Main outcome variables

PTA level: WRS level: Vitamin D level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110603006699N5**

Registration date: **2021-03-09, 1399/12/19**

Registration timing: **prospective**

Last update: **2021-03-09, 1399/12/19**

Update count: **0**

##### Registration date

2021-03-09, 1399/12/19

##### Registrant information

###### Name

Mehrdad Rogha

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3664 0352

###### Email address

rogha@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-10, 1399/12/20

##### Expected recruitment end date

2021-09-22, 1400/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison and evaluation of the effect of rivaroxaban in the complementary treatment of sudden sensorineural hearing loss

##### Public title

The effect of rivaroxaban on hearing loss

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Diagnosis of SNHL by an ENT specialist  
 Reduction of more than 30 dB in hearing at least 3 frequencies  
 Body mass index between 18-30 kg per square meter  
 Negative pregnancy test in women of reproductive age 15-35 years  
 Normal coagulation tests  
 Normal renal function  
 Regular visits for follow up  
 Consent to enter the study

**Exclusion criteria:**

Previous hemorrhagic diseases such as intracranial hemorrhage  
 Previous coagulation diseases  
 History of previous thrombosis anywhere on the body  
 Active stomach ulcers  
 History of psychiatric diseases  
 Any previous illness or surgery on the ears  
 Any signs of inflammation or infection of the ear on examination  
 History of hearing loss  
 Meniere's disease  
 Recent vocal or compressive trauma  
 Underlying disease that may be the cause of SNHL, such as trauma, autotoxic drugs, infection, etc  
 Blood pressure higher than 180/110  
 Uncontrolled diabetes  
 Hypersensitivity reaction to corticosteroids  
 Taking drugs such as methadone

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **34**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, patients and researchers are unaware of the type of drug or placebo used, and the drugs are coded with the same shape and packaging.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan university of medical

science

**Street address**

hezar jirib Ave, Isfahan university of medical science

**City**

Isfahan

**Province**

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**Postal code**

81746-73461

**Approval date**

2020-10-17, 1399/07/26

**Ethics committee reference number**

ir.mui.med.rec.1399.631

**Health conditions studied****1****Description of health condition studied**

Decreased sensorineural hearing

**ICD-10 code**

H90.5

**ICD-10 code description**

Unspecified sensorineural hearing loss

**Primary outcomes****1****Description**

Pure tone audiometry Level

**Timepoint**

Beginning and end of the study

**Method of measurement**

Audiometric device

**2****Description**

Word recognition score level

**Timepoint**

Beginning and end of the study

**Method of measurement**

Audiometric device

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Rivaroxaban 10 mg tablets of the Arena company are received daily for 10 days.

**Category**

Treatment - Drugs

**2****Description**

Control group: Placebo tablets with the same shape and color are taken daily for 10 days. Placebo has been prepared in the laboratory of the Faculty of Pharmacy, University of Isfahan.

**Category**

Placebo

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

Kashani hospital

**Full name of responsible person**

Ehsan moshtaghi

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Ayatollah Kashani Hospital, Ayatollah Kashani Main Street

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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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Esfahan University of Medical Science , Hezar Jerib street , Isfahan , Iran

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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**

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**

Ehsan moshtaghi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

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**Full name of responsible person**

Mehrdad Rogha

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Position**

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**Other areas of specialty/work**

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**Web page address****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**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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