

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

Isfahan

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

Street address

Ayatollah Kashani Hospital, Ayatollah Kashani Main Street

City

Esfahan

Province

Isfahan

Postal code

۸۳۴۳۴۸۱۸۳۹

Phone

+98 31 3233 0091

Email

ehsan_moshtaghi1989@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

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

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

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

Ehsan moshtaghi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

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

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

0098312330066

Email

ehsan_moshtaghi1989@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mehrdad Rogha

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Hezar jarib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3664 0352

Fax

+98 31 3233 9021

Email

rogha@med.mui.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mehrdad Rogha,MD

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Otolaryngology ward, Kashani Hospital,Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98312330066

Fax**Email**

rogha@med.mui.ac.ir

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