

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Assessment of the effect of rivaroxaban as Adjuvant Treatment for improvement of Idiopathic Sudden Sensorineural Hearing Loss

#### Protocol summary

##### Study aim

Assessment of the effect of rivaroxaban as adjuvant treatment for improvement of Idiopathic sudden sensorineural hearing loss

##### Design

Clinical trial with control group, with parallel group, double blind, randomized group, 3 phase on 140 patients.

##### Settings and conduct

140 patients who have referred to the emergency department of AmirAl-Momenin hospital in Rasht with sudden hearing loss are randomly divided into 2 groups. Patients hearing status will be assessed with audiometry before starting treatment and 2 weeks after and 3 months after starting treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18 to 65 years of age with a unilateral sudden sensory hearing loss that Less than 5 days have passed since the onset of the patient's symptoms and a hearing loss of  $\geq 30$  dB at least in 3 consecutive frequencies in the audiometry Exclusion criteria: history of hearing loss, trauma to the ear, active ear infection, congenital cochlear disease Use of ototoxic drugs, anticoagulants, anticonvulsants. Cardiovascular disease, coagulation disorders, and diabetes Retrocochlear lesions Severe renal and hepatic impairment People with neoplasms who have not been treated or are being treated with chemotherapy or radiotherapy pregnancy and Breastfeeding history of autoimmune disorder platelet count disorder

##### Intervention groups

The first group received standard oral treatment with prednisolone at a dose of 1 mg / kg daily (maximum 60 mg as a single dose in the morning) for 10 days and then taper for 5 days (10 mg daily decreases) and valaciclovir 500 mg each. 8 hours (3 times a day) for 7 days and pantoprazole 40 mg daily (for 15 days) and in addition to the above treatment, rivaroxaban is prescribed at a dose of 20 mg daily for 10 days. In the second group, standard

treatment and placebo with the same form as rivaroxaban are given.

##### Main outcome variables

Pure tone audiometry

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200708048051N1**

Registration date: **2020-08-01, 1399/05/11**

Registration timing: **prospective**

Last update: **2020-08-01, 1399/05/11**

Update count: **0**

##### Registration date

2020-08-01, 1399/05/11

##### Registrant information

##### Name

Malihe Akbarpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3261 9301

##### Email address

akbarpour@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2021-08-23, 1400/06/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Assessment of the effect of rivaroxaban as Adjuvant Treatment for improvement of Idiopathic Sudden Sensorineural Hearing Loss

**Public title**

Assessment of the effect of rivaroxaban on sudden sensorineural hearing loss

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with a unilateral sudden sensory hearing loss Refer to the hospital in less than 5 days from the onset of symptoms Hearing loss of  $\geq 30$  dB at least 3 consecutive frequencies in the audiometry.

**Exclusion criteria:**

Patients with a history of hearing loss, trauma to the ear, active ear infection, congenital cochlear disease Use of ototoxic drugs, anticoagulants, anticonvulsants. Cardiovascular disease, coagulation disorders, and diabetes. Retro cochlear lesions Severe renal and hepatic impairment (Cr clearance less than 15) People with neoplasms who have not been treated or are being treated with chemotherapy or radiotherapy. pregnancy and breastfeeding Patients with history of autoimmune disorder Patients with platelet count disorder (less than 150,000)

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **140**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After receiving the explanations about the project, the mentioned patients are divided into two control group and intervention group by permuted block randomization. Blocking is usually used to balance in number of assigned samples to each one of studied groups. This feature helps researchers to in cases that mid-term analyzes are required during the sampling process, number of samples assigned to each of the study groups be equal, First, the software prepares a list of 4 blocks in which an equal number of people are randomly placed in two groups A and B. This list is placed in a separate envelope and then the envelope is closed

and given to a third party. If the patient is referred to and qualified, one of the pocket is given to the patient, according to the number. After filling the forms, the pocket is opened and a patient is treated according to the desired number and receives the related intervention. Patients and researchers will not be informed of the type of received intervention.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

individuals under study, physicians caring for patients and those assessing outcomes and study researchers are kept blind to specific study groups. after selecting patients medications are given to patients in un named and similar envelopes by third person, and the list of patients in each group will not be disclosed until the end of data analysis.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Guilan University of Medical Sciences

**Street address**

Vice-chancellor for Research Building, opposite of Sepah Bank, Shahid Beheshti Blvd

**City**

Rasht

**Province**

Guilan

**Postal code**

4139637459

**Approval date**

2020-07-01, 1399/04/11

**Ethics committee reference number**

IR.GUMS.REC.1399.131

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

Idiopathic Sudden Sensorineural Hearing Loss

**ICD-10 code**

H91.20

**ICD-10 code description**

Sudden idiopathic hearing loss, unspecified ear

## Primary outcomes

### 1

#### Description

Hearing threshold

#### Timepoint

Before starting treatment and 2 weeks after and 3 months after starting treatment

#### Method of measurement

Pure tone audiometry

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Prednisolone (Nisopred ®, Iranhormone Co.) tablets at a dose of 1 mg / kg daily (maximum 60 mg as a single dose in the morning) for 10 days and then taper for 5 days (10 mg daily decreases) and valaciclovir (Virabex ® , Abidi Co.) 500 mg every 8 hours (3 times a day ) For 7 days and pantoprazole (Abidi Co.) 40 mg daily (for 15 days) and rivaroxaban (Xalerban ®, Abidi Co.) at a dose of 20 mg daily for 10 days

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Prednisolone (Nisopred ®, Iranhormone Co.) tablets at a dose of 1 mg / kg daily (maximum 60 mg as a single dose in the morning) for 10 days and then taper for 5 days (10 mg daily decreases) and valaciclovir (Virabex ® , Abidi Co.) 500 mg every 8 hours (3 times a day ) For 7 days and pantoprazole (Abidi Co.) 40 mg daily (for 15 days) and placebo with the same form as rivaroxaban for 10 days

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amiralmomenin Hospital

##### Full name of responsible person

Mir Mohammad Jalali

##### Street address

Amiralmomenin Hospital, 17 Shahrivar Ave, Emam Khomeini Ave

##### City

Rasht

##### Province

Guilan

##### Postal code

4139637459

##### Phone

+98 13 3323 8306

##### Email

mmjalali@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Mohammad reza naghi pour

##### Street address

Namjoo, Blvd.Shahid Siadati Ave, Opposite of Sepah Bank, Vice-chancellor for Research Building

##### City

Rasht

##### Province

Guilan

##### Postal code

4139637459

##### Phone

+98 13 3333 5821

##### Fax

+98 13 3333 6395

##### Email

naghi@gums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Rasht 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

Rasht University of Medical Sciences

##### Full name of responsible person

Dr. Mir Mohammad Jalali

##### Position

Professor

##### Latest degree

Subspecialist

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

Amiralamomenin Hospital, 17 Shahrivar St

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**Province**

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**Postal code**

41396-37459

**Phone**

+98 13 3322 5242

**Email**

mmjalali@gmail.com

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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akbarpour\_malihe@yahoo.com

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

Rasht University of Medical Sciences

**Full name of responsible person**

Dr. Mir Mohammad Jalali

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

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**Postal code**

4139637459

**Phone**

+98 13 3323 8306

**Email**

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

Rasht University of Medical Sciences

**Full name of responsible person**

Malihe Akbarpoor

**Position**

Assistant Professor

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

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

**Title and more details about the data/document**

after the end of the study period

**When the data will become available and for how long**

after the end of the study period

**To whom data/document is available**

After the end of the study period, the results will be available to the public in the form of articles

**Under which criteria data/document could be used**

If published as an article

**From where data/document is obtainable**

ENT Research Center of Guilan University of Medical Sciences

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

In-person referral or electronic request to the ENT

Research Center of Guilan University of Medical Sciences

**Comments**