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: Patients18 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 ≥ 30 dB at least in 3 consecutive frequencies in the audiometery 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 diabete 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

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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 ≥ 30 dB at least 3 consecutive frequencies in the audiometery.
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
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Amiralmomenin Hospital, 17 Shahrivar Ave, Emam Khomeini Ave
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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
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Fax
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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
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
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

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Other areas of specialty/work
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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