Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Assessment of Acyclovir efficacy versus placebo in controlling vertigo attacks of patients with Meniere's Disease visited in Amiralam hospital

Protocol summary

Summary

Meniere’s disease is a chronic illness that affects a substantial number of patients every year worldwide. The disease is characterized by intermittent episodes of vertigo lasting from minutes to hours, with fluctuating sensorineural hearing loss, tinnitus, and aural pressure. It has recently been suggested that viral etiologies specially Herpes virus might be the underlying reason. Our study is a randomized, double- blinded placebo-controlled clinical trial in Amiralam Hospital. In this study the primary objective is to assess efficacy of Acyclovir in control of symptoms in patients with Meniere's disease specially their vertigo attacks. Inclusion criteria would be patient’s willingness to participate in the study and follow ups, being 18 years old or older, having at least 2 vertigos per month each at least 20 min, interfering with function, and not on medication for Meniere's disease for at least 3 months before the trial. They should not have any history of allergy to Acyclovir, renal insufficiency or Creatinine above 1.5 mg/dl, hepatic enzymes more than three times normal, serious uncontrolled illness, be pregnant or nursing or have previous surgeries on Endolymphatic Sac. Participants will be randomly placed in 2 different arms getting either Acyclovir 400 mg or placebo (inert ingredient). They will take the medication for 10 days 5 times a day, then 3 times a day for next 10 days, and 2 times a day for the last 10 days. Patients will report changes in their vertigo attacks, tinnitus, and hearing loss 10 days after initiating the drug and also in follow up visits done one month, three months, and six months after initiating the therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901023597N1**
Registration date: **2012-11-20, 1391/08/30**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2012-11-20, 1391/08/30

Registrant information

Name

Masoud Motasadi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Otorhinolaryngology Research Center,Tehran University of Medical Sciences

Expected recruitment start date

2011-08-02, 1390/05/11

Expected recruitment end date

2012-12-22, 1391/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Acyclovir efficacy versus placebo in controlling vertigo attacks of patients with Meniere's Disease visited in Amiralam hospital

Public title

Efficacy of antiviral medications in controlling vertigo attacks of patients with Meniere's Disease

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:1. Patients' willingness to participate in the study 2. Willingness to participate in follow ups 3. Age of 18 or older 4. Having at least 2 vertigos per month each lasting for at least 20 minutes, severely interfering with function 5. Not on medication for at least 3 months before starting the trial. Exclusion Criteria: 1. History of Allergy to Acyclovir or the drugs in the same category 2. Renal insufficiency or having Creatinine more than 1.5 mg/dl 3. Hepatic enzymes more than 3 times normal 4. Hematocrit less than 30% 5. Thrombocytopenia 6. Having a serious uncontrolled illness 7. Pregnant or nursing ladies 8. Using Probenecid 9. Previous surgeries on endolymphatic sac.
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
This clinical trial is double blind and neither the patients nor the researchers know who belongs to the placebo arm and who belongs to the Acyclovir arm. Randomization method is block randomization. Only after all the data have been recorded do the researchers learn which individuals are which. In this way researchers will not be biased in their assessment of patients response to the treatment given. Patients in Acyclovir arm will receive Acyclovir 400 mg pills (Zovirax), and the placebo in this study mainly consists of calcium phosphate and Avicel (microcrystalline cellulose). Placebo and Acyclovir pills used in this study are all provided by Farabi Pharmaceutical Company and will be handed to patients in similar pill bottels.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Medical ethics committee of Tehran University of Medical Sciences
Street address
No. 23, 16 Azar St., Keshavarz Blvd., Tehran
City
Tehran
Postal code
Approval date
2010-12-20, 1389/09/29
Ethics committee reference number
8803489453

Health conditions studied

1

Description of health condition studied
Meniere's disease
ICD-10 code
H81.0
ICD-10 code description
Labyrinthine hydrops Ménière's syndrome or vertigo

Primary outcomes

1

Description
Vertigo
Timepoint
Before intervention, 1 month, 3 months and 6 months after the intervention
Method of measurement
Subjective

Secondary outcomes

1

Description
Aural fullness
Timepoint
Before intervention, 1 month, 3 months and 6 months after the intervention
Method of measurement
Subjective evaluation in a 0(with no symptom) to 4 (very severe) scale.

2

Description
incidence of patients experiencing nausea as side effect
Timepoint
Before intervention, 1 month, 3 months and 6 months after the intervention
Method of measurement
Patient's subjective evaluation

3

Description
Tinnitus

Timepoint
Before intervention, 1 month, 3 months and 6 months after the intervention
Method of measurement
Subjective evaluation in a 0 (with no symptom) to 4 (very severe) scale.

4

Description
Change in renal function as a side effect
Timepoint
Before intervention, 1 month, 3 months and 6 months after the intervention
Method of measurement
Renal function test , if history suggestive of that

5

Description
Hearing
Timepoint
Before intervention, 1 month, 3 months and 6 months after the intervention
Method of measurement
Audiometry and also subjective evaluation

Intervention groups

1

Description
Participants who are randomly placed in placebo group, besides having a low salt diet will take the placebo pills (inert ingredient) for 10 days 5 times a day, then 3 times a day for next 10 days, and 2 times a day for the last 10 days. Patients would receive the medication in 2 sessions, first in the beginning of the study and the rest after 10 days. This would increase their compliance, and physicians would be aware of possible complications. Patients will report changes in their symptoms 10 days after initiating the drug and one month, three months and six months after the treatment. All changes in frequency and duration of vertigo attacks are recorded, and tinnitus and aural fullness is recorded in a 0(with no symptom) to 4 (very severe) scale.
Category
Placebo

2

Description
Patients who were randomly allocated to the Acyclovir group besides having low salt diet will take the Acyclovir 400 mg pills (Zovirax) for 10 days 5 times a day, then 3 times a day for next 10 days, and 2 times a day for the last 10 days. Patients would receive the medication in 2 sessions, first in the beginning of the study and the rest after 10 days. This would increase their compliance, and physicians would be aware of possible complications. Patients will report changes in their symptoms 10 days after initiating the drug and one month, three months and six months after the treatment. All changes in frequency and duration of vertigo attacks are recorded, and their tinnitus and aural fullness is recorded in a 0(with no symptom) to 4 (very severe) scale.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralam Hospital
Full name of responsible person
Dr Masoud Motesadi
Street address
Tehran, Enghelab Avenue, North Saadi Avenue, Opposite Bank of Commerce
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Research, Tehran University of Medical Sciences
Full name of responsible person
Dr Akbar Fotouhi
Street address
Ghods St., Keshavarz Blvd.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Amiralam Hospital, Tehran University of Medical Sciences
Full name of responsible person

Dr Masoud Motesadi

Position

Attending Physician

Other areas of specialty/work

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Affiliated researcher

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty