Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of cisplatin otoprotection using intratympanic diltiazem and placebo among patients with solid cancer

Protocol summary

Study aim
Determination and comparison of cisplatin otoprotection using intratympanic diltiazem and placebo among patients with solid cancer

Design
In this study, 25 patients (Cases:25 ears and Controls:25 ears) with solid cancer who were referred to Amiralmomenin Hospital in Rasht are selected. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

Settings and conduct
In this study, 25 patients (Cases:25 ears and Controls:25 ears) with solid cancer who were referred to Amiralmomenin Hospital are evaluated by double-blind randomized clinical trial method. We obtain informed consent from all participants. A comprehensive history taking, including history of ear diseases is taken. Then a physical examination of the ear is performed using a microscope , before each course of course of chemotherapy. Diltiazem Drug is injected middle ear. Then participation is asked to supine on Opposite ear, Avoid Swallow, and Cough for 20 minute. A hearing test is also conducted one week and one month after the last chemotherapy course

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years old; Presence of Acoustic Reflex or Tympanometry A; Average hearing threshold less than 40 dB; The hearing threshold on either side should not be asymetric or there is less than 10 dB; The karnofsky index is equal to or greater than 70 Exclusion criteria: History of previous internal ear; History of Meniere's disease Or Fluctuating hearing loss; Observing Pathologic findings in otoscopy; Previously cisplatin has not been treated; Radiation History to the head and neck Area; Candidate for radiation to the head and neck; Liver and Renal failure; Conductive hearing loss more than 5 dB; Heart problems

Intervention groups
The ear receiving diltiazem solution The ear receiving the placebo

Main outcome variables
Hearing Loss

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20081202001483N4**
Registration date: **2018-09-16, 1397/06/25**
Registration timing: **prospective**

Last update: **2018-09-16, 1397/06/25**
Update count: **0**

Registration date
2018-09-16, 1397/06/25

Registrant information

Name
Mir Mohammad Jalali

Name of organization / entity
Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-09-23, 1398/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of cisplatin otoprotection using intratympanic diltiazem and placebo among patients with solid cancer

Public title
Evaluation of effect injection of diltiazem into middle ear on the hearing loss due to Cisplatin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years old Presence of Acoustic Reflex or Tympanometry A In PTA, average hearing threshold at frequencies of 3000-5000 or 8000 to 4000 less than 40 dB In PTA, the hearing threshold on either side should not be asymetric within 3000 to 5000 or 8000-4000 Hz frequencies or there is less than 10 dB The karnofsky index is equal to or greater than 70
Exclusion criteria:
History of previous internal ear disease that may reduce the sensory nervous system hearing History of Meniere's disease Or fluticating hearing loss Observing pathologic findings in otoscopy Previously cisplatin has not been treated Radiation History to the head and neck Area Candidate for radiation to the head and neck Liver and Renal failure Conductive hearing loss more than 5 dB Heart problems, such as hypotension or AV block
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **25**
More than 1 sample in each individual
Number of samples in each individual: **2**
Control ear and Case ear
Randomization (investigator's opinion)
Randomized
Randomization description
With using of Pass software , randomly assigned control Ear and intervention Ear
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to maintain double blindness in the study, both patients and all researchers will be unaware of the received drug. A researcher will explain about the drug to the patients and assign each ear to control ear or intervention ear according to the Random Number Table (PASS software). Same researcher will inject drug or placebo in middle ear under local anesthesia. Another researcher will evaluate the patients before and after intervention. Audiologist and patients will be blinded about type of intervention of each ear.
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
2018-08-18, 1397/05/27
Ethics committee reference number
IR.GUMS.REC.1397.186

Health conditions studied

1

Description of health condition studied
Hearing Loss
ICD-10 code
H91.0
ICD-10 code description
Ototoxic hearing loss

Primary outcomes

1

Description
Hearing Loss
Timepoint
One week and one month after the last dose of cisplatin
Method of measurement
Audiometry Test

2

Description
Low-frequency Average hearing threshold

Timepoint
One week and one month after the last dose of cisplatin
Method of measurement
Audiometry Test

3

Description
High-frequency Average hearing threshold
Timepoint
One week and one month after the last dose of cisplatin
Method of measurement
Audiometry Test

Secondary outcomes

1

Description
Ototoxicity Grade
Timepoint
One week and one month after the last dose of cisplatin
Method of measurement
Audiometry(Grade changes)

2

Description
Complications of cisplatin injection
Timepoint
One week and one month after the last dose of cisplatin
Method of measurement
Questions From Patient

Intervention groups

1

Description
Intervention group: At first, Case-ear is filled with Xyla-P ointment. After 5 minute local anesthesia , ointment was suctioned under microscope. 0.7-1 cc of Diltiazem solution (5mg/ml) is injected through inferior-posterior quadrant of tympanic membrane into middle ear(near round niches). Then participation is asked to supine on opposite ear, avoid swallow, and cough for 20 minute
Category
Treatment - Drugs

2

Description
Control group: At first, control-ear is filled with Xyla-P ointment. After 5 minute local anesthesia , ointment was suctioned under microscope
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin Hospital
Full name of responsible person
Dr Mirmohammad Jalali
Street address
Amiralmomenin Hospital, 17 Shahrivar Ave, Emam Khomeini Ave
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2

Recruitment center
Name of recruitment center
Razi Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Susan Komaee
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komaikoma@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
Iran University of Medical Sciences
Full name of responsible person
Dr Mirmohammad Jalali
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
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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