

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 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 asymmetric 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)

Phone

+98 13 1324 3085

Email address

mmjalali@gums.ac.ir

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 asymmetric 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 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, such as hypotension or AV block

AgeFrom **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

City

Rasht

Province

Guilan

Postal code

4139637459

Phone

+98 13 3322 5242

Email

mmjalali@gmail.com

2

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr Mirmohammad Jalali

Street address

Razi Hospital, Sardarjanganal Ave

City

Rasht

Province

Guilan

Postal code

41448413963

Phone

+98 13 3355 0028

Email

mmjalali@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Susan Komaee

Street address

Shahid Beheshti Blvd.(west), opposite of Sepah Bank, vice-chancellor for Research Building

City

Rasht

Province

Guilan

Postal code

4139637459

Phone

+98 13 3333 0959

Email

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
Ear, Nose, and Throat
Street address
Amiralamomenin Hospital, 17 Shahrivar St
City
Rasht
Province
Guilan
Postal code
41396-37459
Phone
+98 13 3322 5242
Email
mmjalali@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr Mirmohammad Jalali
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Ear, Nose, and Throat
Street address

Amiralamomenin Hospital, 17 Shahrivar St
City
Rasht
Province
Guilan
Postal code
41396-37459
Phone
+98 13 3322 5242
Email
mmjalali@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Fatemeh Nezamdoust
Position
Msc
Latest degree
Master
Other areas of specialty/work
Health Service Management
Street address
Amiralamomenin Hospital, 17 shahrivar St
City
Rasht
Province
Guilan
Postal code
4139637459
Phone
+98 13 3322 5242
Email
fatemeh_nezamdoust@yahoo.com

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