

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Clinical trial Comparison of Sertraline and Placebo to reduce Cisplatin-induced ototoxicity in patients with Cancer

Protocol summary

Summary

The aim of this study was to investigate the preventive effect of Sertraline on Cisplatin-induced ototoxicity. Randomized, single-blind, placebo-controlled, multicenter, Step three trial. A total of 70 patients by blocked randomization divided into two groups. Inclusion criteria: patients with cancer who are scheduled to receive Cisplatin; aged 20 to 65 years. Exclusion criteria: use of other ototoxic drugs or drugs that interfere with the use of Sertraline or Cisplatin, associated comorbidities, pregnancy or lactation, history of radiotherapy. Coinciding with the start of Cisplatin Sertraline start with 25 mg once daily for the case group and if tolerated after three days increased to 50 mg per day and the drug continues during chemotherapy (3 months) . For the control group given a placebo for three months. Patients before beginning of Cisplatin and after completion of the drug and placebo Course placed under high frequency Tympano audiometry and Distortion Product Otoacoustic Emissions (dpOAE) and the results of the hearing loss (primary variable) and treatment complications (secondary variable) will be statistically analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081927286N1**

Registration date: **2016-10-29, 1395/08/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-29, 1395/08/08

Registrant information

Name

Zahra Karbasi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial Comparison of Sertraline and Placebo to reduce Cisplatin-induced ototoxicity in patients with Cancer

Public title

Prevention of Cisplatin-induced ototoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with cancer who are scheduled to receive Cisplatin; aged 20 to 65 years. Exclusion criteria: previous use of Cisplatin or any ototoxic drug; patients with Head and Neck cancer; age above 65 years; patients who use hearing aids or those associated

with hearing loss in the past otalgic disease; Steroid user; patients with systemic diseases such as Diabetes, Hypertension, Thyroid disease, Kidney or Liver disease; pregnant or lactating women; patients with a history of Seizure; taking Monoamine Oxidase inhibitors; concomitant use of Antidepressants drugs; history of radiotherapy.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Department of Research and Technology, 5th Floor, between the intersection of Sheikh Fazlollah and Martyr Chamran, West Martyr Hemmat Highway, Tehran

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Tehran

Postal code

1449614535

Approval date

2016-09-04, 1395/06/14

Ethics committee reference number

IR.IUMS.REC 1395.9311369005

Health conditions studied

1

Description of health condition studied

Hearing loss

ICD-10 code

C85

ICD-10 code description

Other and unspecified types of non-Hodgkin lymphoma

2

Description of health condition studied

Hearing loss

ICD-10 code

C81

ICD-10 code description

Hodgkin lymphoma

3

Description of health condition studied

Hearing loss

ICD-10 code

C83

ICD-10 code description

Non-follicular lymphoma

4

Description of health condition studied

Hearing loss

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

Primary outcomes

1

Description

Hearing frequency

Timepoint

Before the intervention, After the intervention

Method of measurement

Distorsion product Otoacoustic Emission, High frequency tympanoaudiometry

Secondary outcomes

1

Description

The side effects of taking Sertraline

Timepoint

Before the intervention, After the intervention

Method of measurement

Interview

Intervention groups

1

Description

Case groups: Sertraline, 50 mg oral tablet, starting dose with 25 mg once daily and if tolerated 50 mg per day continues for 3 months

Category

Prevention

2**Description**

Control group: placebo, Saccharin oral tablet, a daily pill for three months

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Prophet Muhammad (PBUH) Hospital

Full name of responsible person

Zahra Karbasi

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2**Recruitment center****Name of recruitment center**

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Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Investigator

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**

Medical System

Full name of responsible person

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Position

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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