

# 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

Iran Univerciy of Medical Sience

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6435 2122

##### Email address

karbasi.z@iums.ac.ir

##### 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

##### **City**

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

**Street address**

Prophet Muhammad (PBUH) Research and Treatment Educational Centers, Street of Worship, Sattarkhan, Tehran

**City**

Tehran

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

Firoozgar Hospital

**Full name of responsible person**

Zahra Karbasi

**Street address**

Firoozgar Hospital, Behafarin Street, Karim Khan Zand Street, Vali Asr Street, Tehran

**City**

Tehran

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

Investigator

**Full name of responsible person**

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**City**

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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**

Zahra Karbasi

**Position**

Clinical Assistant

**Other areas of specialty/work****Street address**

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Karbasi.z@iums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Position**

Assistant Professor

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## Person responsible for updating data

### Contact

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Clinical Assistant

**Other areas of specialty/work**

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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*