# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 May 2026

## Effect of Ginkgo Biloba extract in comparison with placebo on prevention of tinnitus and otoxicity in patients treated with cisplatin

## Protocol summary

**Summary**

48 cancer patients aged over 18 years who are candidates receiving cisplatin regimen with written consent will enter to the study. After taking hearing history and ear examination, audiometry and DPOAE tests; and filling the questionnaire tinnitus, if the above parametrs are within normal ranges patients,randomly, will distribute into two 24 persons groups.We will use the protocols of http://www.randomization.com for randomization (Block design). We will use Ginkgo T.D. tablets produced by Toliddaru Iran.Each tablet contains 40 mg Ginkgo Biloba leaf extract. The Placebo will be produced by Toliddaru and for blindness of the patients and examiners ,it will have the same packing,shape,taste,color and preservatives like the drug. At the beginning of a cisplatin regimen 240 mg of Ginkgo Biloba extract will give to patients daily in case group( 2 tablets TDS) and in the placebo group starch will give to patients daily (2 tablets TDS). Before starting each course of cisplatin regimen and six months after the completion of the above tests and questionnaires will be filled. At the end of the study, the results of DPOAE, audiometry and tinnitus severity of side effects between the two groups in any of the Impact Ginkgo Biloba extract will be reported.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015020720982N1**
Registration date: **2015-11-02, 1394/08/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2015-11-02, 1394/08/11

**Registrant information**

**Name**
Mahtab Rabbani Anari
**Name of organization / entity**
Tehran Univesity of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 6119 2393
**Email address**
m_rabani@razi.tums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Tehran University of Medical Sciences

**Expected recruitment start date**

2015-11-01, 1394/08/10

**Expected recruitment end date**

2018-04-01, 1397/01/12

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of Ginkgo Biloba extract in comparison with placebo on prevention of tinnitus and otoxicity in patients treated with cisplatin

**Public title**

Effect of Ginkgo Biloba extract in comparison with placebo on prevention of tinnitus and ototoxicity in patients treated with cisplatin

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: People over the age of 18 candidates for treatment with cisplatin regimen for first time

Exclusion criteria: Middle ear disorders Head and neck cancers Gastrointestinal problems Tendency to bleeding Concomitant use of other ototoxic drugs History of Ginkgo Biloba consumption Inability to record DPOAE

**Age**
No age limit
**Gender**
Both

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **48**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
The committee of "Ethic in research" of TUMS
**Street address**
Tehran University of Medical Sciences
**City**
Tehran
**Postal code**
**Approval date**
2015-06-01, 1394/03/11
**Ethics committee reference number**
94-01-48-28864-151125

### 2

**Ethics committee**
**Name of ethics committee**
The committee of "Ethic in research" of TUMS
**Street address**
Tehran University of Medical Sciences
**City**
Tehran
**Postal code**
**Approval date**
2015-06-01, 1394/03/11
**Ethics committee reference number**
94-01-48-28864-151125

## Health conditions studied

### 1

**Description of health condition studied**
Prevention of ototoxicity of cisplatin
**ICD-10 code**
H91.0
**ICD-10 code description**
Ototoxic hearing loss

## Primary outcomes

### 1

**Description**
DPOAE
**Timepoint**
Before beginning of each chemotherapy course and 6 month after ending
**Method of measurement**
By Audiometry devise in decibel scale

### 2

**Description**
Tinnitus severity
**Timepoint**
Before beginning of each chemotherapy course and 6 month after ending
**Method of measurement**
From 0 to 100

### 3

**Description**
Ototoxicity severity
**Timepoint**
Before beginning of each chemotherapy course and 6 month after ending
**Method of measurement**
By Pure tone audiometry grading from 0 to 4

## Secondary outcomes

### 1

**Description**
Drug side effects including Gastrointestinal and bleeding
**Timepoint**
Whole period of Ginkgo Biloba consumption
**Method of measurement**
Questionnaire

### 2

**Description**
Age
**Timepoint**
Before entering to study
**Method of measurement**
Questionnaire

**3**

**Description**
Sex
**Timepoint**
Before entering to study
**Method of measurement**
Questionnaire

**4**

**Description**
Anxiety
**Timepoint**
Before beginning of each chemotherapy course and 6 month after ending
**Method of measurement**
Anxiety questennaire

**5**

**Description**
Self esteem
**Timepoint**
Before beginning of each chemotherapy course and 6 month after ending
**Method of measurement**
Self esteem questionnaire

**6**

**Description**
Depression
**Timepoint**
Before beginning of each chemotherapy course and 6 month after ending
**Method of measurement**
Depression questionnare

**7**

**Description**
cis platin dose
**Timepoint**
Before beginning of each chemotherapy course
**Method of measurement**
In mg/ mm2

**8**

**Description**
Cancer type
**Timepoint**
Before entering to study
**Method of measurement**
Pathology report

**9**

**Description**
Medical history
**Timepoint**
Before entering to study
**Method of measurement**
Questionnaire

**10**

**Description**
Drug history
**Timepoint**
Before beginning of each chemotherapy course and 6 month after ending
**Method of measurement**
Questionnaire

**11**

**Description**
Renal and liver laboratory data
**Timepoint**
Before beginning of each chemotherapy course and 6 month after ending
**Method of measurement**
Laboratory ( Urea, Creatinin and liver enzymes)

## Intervention groups

**1**

**Description**
Intervention group: Ginckgo Biloba prescription (2 tablets per 8 hours)
**Category**
Treatment - Drugs

**2**

**Description**
Control Group: Placebo prescription, 2 tablets per 8 hours
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Cancer institute
**Full name of responsible person**
Dr Sanambar Sedighi
**Street address**
Imam Khomeyni Hospital
**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**

Dr Mahtab Rabbani Anari

**Street address**

Blv Keshavarz- Poor Sina Ave- Tehtran University of Medical Sciences

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**

Theran University of Medical Sceinces

**Full name of responsible person**

Dr Mahtab Rabbani Anari

**Position**

Assisstant Professor

**Other areas of specialty/work**

**Street address**

Imam Khomeyni Hospital - Ear, nose and throat ward

**City**

Tehran

**Postal code**

**Phone**

+98 21 6119 2393

**Fax**

**Email**

m_rabani@razi.tums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Theran University of Medical Sceinces

**Full name of responsible person**

Dr Mahtab Rabbani Anari

**Position**

Assisstant Professor

**Other areas of specialty/work**

**Street address**

Imam Khomeyni Hospital - Ear, nose and throat ward

**City**

Tehran

**Postal code**

**Phone**

+98 21 6119 2393

**Fax**

**Email**

m_rabani@razi.tums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Reza Erfanian

**Position**

Residence of ear, nose and throat

**Other areas of specialty/work**

**Street address**

Imam Khomeyni Hospital - Ear, nose and throat ward

**City**

Tehran

**Postal code**

**Phone**

+98 21 6693 1115

**Fax**

**Email**

rezakhosravimd@gmail.com

**Web page address**

## 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*