

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of Ginkgo Biloba extract in comparison with placebo on prevention of tinnitus and ototoxicity 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 parameters 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 University 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 ototoxicity 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 questonnaire

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

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**Person responsible for scientific
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Person responsible for updating data

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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