

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the efficacy of ginseng supplement in the prevention of cardiac toxicity induced by anthracyclines in breast cancer patients

Protocol summary

Study aim

Oxidative stress is known as the most acceptable mechanism of anthracycline-induced cardiotoxicity. Considering the anti-oxidant and anti-inflammatory effects of ginseng supplement, the purpose of this study is to evaluate the effect of ginseng supplement in the prevention of anthracycline-induced cardiotoxicity in non-metastatic breast cancer patients.

Design

This is a randomized, double blind, placebo controlled clinical trial.

Settings and conduct

Participants, care provider, outcome assessors and analysts are blinded in this study.

Participants/Inclusion and exclusion criteria

Sixty two patients aged 18 to 65 years with non-metastatic breast cancer who have received their first course of anthracycline based chemotherapy regimen will be randomly assigned into two groups; the intervention and the control group. The patients with the following factors will be excluded from the study: history of anthracyclines therapy, history of having solid tumors that received systemic therapy, metastatic or recurrent breast cancer, LVEF below 50%, history of chronic diseases (DM, cardiac disease, renal failure), pregnant and breast-feeding women.

Intervention groups

The intervention group will be received 1g ginseng daily (4 capsules containing 250 mg of ginseng rhizome powder, standardized based on 6.3-7.7 mg ginsenoside of Rg1) and the control group will be received 1g placebo daily (4 capsules containing 250 mg starch) beside the standard chemotherapy regimen for 3 months (until the end of the last chemotherapy course which has 4 cycles administered each 3 weeks).

Main outcome variables

Cardiotoxicity evaluation with LVEF and Trop I will be assessed baseline and after completion of the 3 months chemotherapy course.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141227020441N7**

Registration date: **2020-01-19, 1398/10/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-19, 1398/10/29**

Update count: **0**

Registration date

2020-01-19, 1398/10/29

Registrant information

Name

Farzaneh Foroughinia

Name of organization / entity

Shiraz University of Medical Sciences

Country

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foroughinia@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of ginseng supplement in the prevention of cardiac toxicity induced by anthracyclines in breast cancer patients

Public title

The efficacy of ginseng supplement in the prevention of cardiac toxicity induced by anthracyclines

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The ages of 18 to 65 years Patients with non-metastatic breast cancer Receiving the first course of anthracycline based chemotherapy

Exclusion criteria:

History of therapy with anthracyclines Metastatic or recurrent breast cancer History of solid tumors and receiving systemic therapy LVEF below 50% History of chronic diseases (DM, cardiac disease. renal failure) Pregnancy and lactation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is conducted by the table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, care provider, outcome assessor and data analyser are blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Deputy for research, Central building of Shiraz

University of Medical Sciences, Zand avenue, Shiraz

Street address

Shiraz University of Medical Sciences, Deputy for research

City

Shiraz

Province

Fars

Postal code

7146864685

Approval date

2019-02-13, 1397/11/24

Ethics committee reference number

IR.SUMS.REC.1398.609

Health conditions studied

1

Description of health condition studied

cardiac disease

ICD-10 code

I42.7

ICD-10 code description

Cardiomyopathy due to drug and external agent

Primary outcomes

1

Description

Cardiotoxicity will be assessed based on LVEF and Trop I

Timepoint

will be evaluated baseline and after completion of chemotherapy cycles (3 months).

Method of measurement

LVEF and Trop I will be assessed with echocardiography and blood samples respectively.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The standard chemotherapy regimen beside 1g ginseng daily for 3 months

Category

Prevention

2

Description

Control group: The standard chemotherapy regimen beside 1g capsules containing starch daily for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir hospital

Full name of responsible person

Farzaneh Foroughinia

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Amir hospital, in front of Kowsar pool, Rajaei Blvd,
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Sponsors / Funding sources

1

Sponsor

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Grant name

Shiraz University of Medical Sciences, Vice Chancellor of
Research

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Foroughinia

Position

Assistant Professor

Latest degree

Specialist

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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