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 wemon.

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 coarse 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 coarse.

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

Iran (Islamic Republic of)

Phone

+98 71 3635 9357

Email address

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
Paticipants, 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 monthes).

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 monthes

Category
Prevention

2

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

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir hospital

Full name of responsible person
Farzaneh Foroughinia

Street address
Amir hospital, in front of Kowsar pool, Rajaei Blvd, Shiraz, Fars, Iran

City
Shiraz

Province
Fars

Postal code
۷۱۸۷۹۱۵۹۹۸

Phone
+98 71 3632 3532

Email
foroughinia@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Farzaneh Foroughinia

Street address
Karafarin street, School of pharmacy

City
Shiraz

Province
Fars

Postal code
7134814336

Phone
+98 71 3230 5410

Fax
+98 17 3242 6122

Email
foroughinia@sums.ac.ir

Grant name
Shiraz University of Medical Sciences, Vice Chancellor of Research

Grant code / Reference number
empty

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

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, Shiraz University of Medical Sciences

City
Shiraz

Province
Fars

Postal code
7146864685

Phone
+98 7132424128233

Email
foroughinia@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Farzaneh Foroughinia

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, Shiraz University of Medical Sciences

City
Shiraz

Province
Fars

Postal code
7146864685

Phone
+98 71 3230 5410

Email
foroughinia@sums.ac.ir

Person responsible for updating data

foroughinia@sums.ac.ir

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Farzaneh Foroughinia

Position
Assistant Profesoor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, Shiraz University of Medical Sciences

City
Shiraz

Province
Fars

Postal code
7146864685

Phone
+98 71 3242 4128

Email

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