

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Cardioprotective effect of quercetin supplement in against of cardiac induced toxicity of doxorubicin in breast cancer patients: a randomized, double-blinded, placebo-controlled trial.

Protocol summary

Study aim

this study is to investigate the effect of Quercetin cardiac protection as an oral supplement in breast cancer patients undergoing chemotherapy with Doxorubicin.

Design

Randomized clinical trial (phase II), with parallel intervention (30 subjects) and placebo groups (30 subjects), double-blind.

Settings and conduct

The study is double blind (all patients and researchers). Treatment with oral supplementation Quercetin is started 1 week before the onset of chemotherapy at a dose of 250 mg daily to the end of the chemotherapy (3 months) period. All patients are under treatment protocol (60 mg / m²) with Doxorubicin + cyclophosphamide (2600 mg / m²) every 3 weeks for 4 periods. To evaluate cardiac effects and cumulative dose of the drug, echocardiography is performed for all patients at first and 24 hours prior to the start of chemotherapy as well as the end of the chemotherapy (end of 3 months) and 6 months and one year after the end of the treatment period. The study is carried out at Razi hospital laboratory.

Participants/Inclusion and exclusion criteria

Eligible patients include women aged 21-69 years with sinus rhythm and normal ventricular drainage fraction, normal liver and kidney function, and normal hematology.

Intervention groups

Eligible patients are randomly divided into two groups of intervention and placebo with equal ratios. Patients in the intervention group take quercetin oral supplement. Quercetin oral supplementation is continued 2 weeks prior to the onset of chemotherapy at a dose of 250 mg (once a day) from the beginning and end of the chemotherapy (3 months) period, and the patients in the control group receive placebo two weeks before the end

of the course.

Main outcome variables

Cardiac toxicity of doxorubicin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190303042892N1**

Registration date: **2019-03-11, 1397/12/20**

Registration timing: **retrospective**

Last update: **2019-03-11, 1397/12/20**

Update count: **0**

Registration date

2019-03-11, 1397/12/20

Registrant information

Name

Mona Haddad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3361 8177

Email address

haddad@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-16, 1397/02/26

Expected recruitment end date

2019-03-05, 1397/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cardioprotective effect of quercetin supplement in against of cardiac induced toxicity of doxorubicin in breast cancer patients: a randomized, double-blinded, placebo-controlled trial.

Public title

The effect of co-administration of quercetin supplemented cardiac cardiovascular system with cardiotoxicity of doxorubicin in patients with breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Eligible patients include women aged 21-69 years with sinus rhythm and normal ventricular drainage fraction, normal liver and kidney function, and normal hematology. Previously don't have any document for chemotherapy or radiotherapy for other types of malignancies. They don't have CHF. Have not experienced myocardial infarction. Do not suffer from obstruction or heart valves stenosis. They don't have specific disease or specific drug therapy that affects cardiac function. EF do not have less than 55%. They don't have cardiovascular disease risk factors, such as hypertension, high fat, and do not include smokers. Women in this clinical trial study are not pregnant and don't have systolic pressure of less than 90 mmHg.

Exclusion criteria:

Unwillingness to appear in the plan, to make any changes to the treatment or use of the drug. At any time from the implementation of the plan, in the event of any unwanted side effects, the oral supplement will be discontinued and the patient will be excluded from the study.

AgeFrom **1360 years** old to **1360 years** old**Gender**

Female

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

Limited Randomization is done in which both groups have the same sample size and the random allocation rule is also used to balance the number of people assigned to each group. For this purpose, SAS software and websites www.grahpad.com/quickcalcs/index.cf are used. Moreover, the SNOSE method is used to hide the

allocation, the use of non-transparent sealed packets with random sequences.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this randomized clinical trial, placebo-controlled (Phase II), which is done in double blind (all patients and researchers are blinded to studying), of 100 women with breast cancer (C50-C50 disease code); Malignant neoplasm of breast). With the initial diagnosis and referral to the Behesht Clinic of Rasht in year 2018, which will be treated with anthracycline (doxorubicin) will be used.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Guilan University of Medical Sciences

Street address

Dr. Heshmat Rasht Hospital -Masala Square, Baniyan St

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Guilan

Postal code

41939-5558

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

IR.GUMS.REC.1397.455

Health conditions studied**1****Description of health condition studied**

Patients with Breast Cancer

ICD-10 code

C50.9

ICD-10 code description

Breast, unspecified

Primary outcomes**1****Description**

The cardiac toxicity of doxorubicin is a primary outcome.

Timepoint

The amount of troponin is measured one month after the start of chemotherapy and the end of the course.

Method of measurement
Troponin test

Secondary outcomes

1

Description

Quercetin cardiovascular effect is a secondary consequence.

Timepoint

Echocardiography will be done at the end of the chemotherapy (first 3 months), 6 months later and one year later

Method of measurement

Echocardiography

Intervention groups

1

Description

Intervention group: Patients in the intervention group receiving oral quercetin supplementation. Oral supplementation Quercetin (pure America manufacturer) continues 2 weeks before starting a chemotherapy dose of 250 mg (once a day) from the beginning and end of the chemotherapy (3 months) period.

Category

Treatment - Drugs

2

Description

Control group: the patients in the control group who received two They will receive a placebo week before the end of the course. Oral supplements of quercetine and placebo are similar in appearance, color and odor.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiovascular Diseases Research Center Guilan
University of Medical Sciences

Full name of responsible person

Mona Hadad Zahmatkesh

Street address

Dr. Heshmat Rasht Hospital -Masala Square, Baniyan St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Vice-chancellor research and technology of the Guilan University

Street address

Rasht, Namjoo Ave., Shahid Siadati St., Faced to the 17th Shahrivar Hospital, Old Building, School of Health, University of Technology Research and Technology

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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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Mona Hadad Zahmatkesh

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable