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-blined, 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 / m 2) 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)

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+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-blined, 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.
Age
From **1360 years** old to **1360 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target 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.graghpad.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
City
Rasht
Province
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

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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