

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation effect of crocin in cardiac complication due to doxorubicin in patients with breast cancer

Protocol summary

Study aim

Evaluation of therapeutic effect of crocin in reduction of cardiac complication due to doxorubicin in patients with breast cancer

Design

A double blind, block randomized, controlled trial, sample size 60, phase 3

Settings and conduct

In this clinical trial, patients with non-metastatic breast cancer who are candidate for receiving chemotherapy with doxorubicin-regimen (AC-TAXOL) will be entered in this research. The treatment regimen of these patients will be according to the oncologist's opinion according to standard protocols that crocin will be added to the regimen of intervention group. Patients will be randomly divided into two groups according to age, sex, stage of disease, etc. The first group will receive standard treatment with placebo and the second group will receive standard treatment with crocin. The daily dose of crocin will be 15 mg for 4 months. The total number of patients in this study will be 60 patients (30 patients per group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Non metastatic breast cancer; female patient; candidate for adjuvant chemotherapy along with regimen containing doxorubicin; Negative HER2 receptor. Exclusion criteria: Unwillingness to enter the study; History of taking psychiatric drugs (anti-anxiety drugs and Anti-depressant); Psychiatric disorders; Underlying heart disease; heart valve disease.

Intervention groups

In the intervention group, patients will receive two capsules of 15mg crocin daily while in the placebo group, patients will receive two capsules (placebo), similar in appearance and form to crocin capsules, along with chemotherapy. The duration of capsule use in both groups will be 4 months.

Main outcome variables

Complications of heart failure (shortness of breath,

reduced EF)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131017015044N5**

Registration date: **2020-02-29, 1398/12/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-29, 1398/12/10**

Update count: **0**

Registration date

2020-02-29, 1398/12/10

Registrant information

Name

Soodabeh Shahidsales

Name of organization / entity

Cancer research center

Country

Iran (Islamic Republic of)

Phone

+98 51 1846 1518

Email address

shahidsales@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation effect of crocin in cardiac complication due to doxorubicin in patients with breast cancer

Public title

Evaluation effect of crocin in cardiac complication due to doxorubicin in patients with breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Non metastatic breast cancer female patient candidate for adjuvant chemotherapy along with regimen containing doxorubicin Negative HER2 receptor

Exclusion criteria:

Unwillingness to enter the study History of taking psychiatric drugs (anti-anxiety drugs and Anti-depressant) Psychiatric disorders Underlying heart disease heart valve disease

Age

From **25 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

permuted block Randomization. In this study the sample size is 60. 15 blocks with 4 cases, in each block 2 of placebo group and 2 of intervention group will be randomly selected.

Blinding (investigator's opinion)

Double blinded

Blinding description

Sequentially numbered, sealed, opaque envelopes. A random sequence will be created by random allocation rule. Then, based on the sample size, 60 envelopes with aluminum foil inside (to prevent "hot lighting") will be prepared. Each entity in the random sequence will be noted on a card and replaced in numbered envelop. Finally, the envelopes will be sealed and placed in boxes, respectively. The envelops are going to respectively assign to each participant so the participant's assigned group will be revealed.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad university of Medical Sciences

Street address

Second Floor, Ghoreishi Building, Daneshgah Street, Mashhad

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Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2019-08-27, 1398/06/05

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.670

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

Breast cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast of unspecified site

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

Complications of heart failure (shortness of breath, reduced EF)

Timepoint

before treatment and 2.5 and 5 months after treatment

Method of measurement

Echocardiography-Electrocardiography- TPI -ProBNP

Secondary outcomes**1****Description**

Other cardiac complications (ischemia)

Timepoint

before treatment and 2.5 and 5 months after treatment

Method of measurement

Echocardiography-Electrocardiography- TPI -ProBNP

Intervention groups

1

Description

Intervention group: Adding crocin to chemotherapy regimen containing doxorubicin. In the intervention group, patients will receive two capsules of 15 mg crocin daily along with chemotherapy drugs. The duration of the consumption will be 4 months.

Category

Treatment - Drugs

2

Description

Control group: chemotherapy regimen containing doxorubicin with placebo. In the control group, patients will receive two capsules daily, similar in appearance to the capsules of crocin, along with chemotherapy drugs. The duration of consumption will be 4 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Fatemeh Molaee

Street address

Omid Hospital, Alandasht intersection, Koohsangi Street

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Mashhad University of Medical Sciences, Khorasan

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Web page address

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Molaee

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Soodabeh Shahidsales

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Molaei

Position

Resident

Latest degree

Medical doctor