Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Assessment of the effectiveness of addition of Crocin to doxorubicin containing chemotherapy regimen on survival of breast cancer patients

Protocol summary

Study aim

This study will be done as a double-blind, randomized, placebo-controlled, clinical trial to determine Crocin treatment effects added to doxorubicin-contained chemotherapy in breast cancer.

Design

This study will be performed on 80 new breast cancer patients after margin negative surgery. Patients will be randomized to crocin or placebo during chemotherapy. In crocin group patients will take two 15 mg tablets daily and in placebo group, pills will be similar to crocin. Treatment length will be 4 months. Before each chemotherapy kidney function test and cellular blood count will be checked. Beck depression and anxiety tests will be taken before the beginning and after chemotherapy treatment and then every 4 months until one year. Besides, the presence and severity of chemotherapy side effects will be adopted from patients profiles. Patients will also be followed up for 3 years.

Settings and conduct

This study will be conducted in oncology clinic of Omid Hospital and Emam Reza Hospital, Mashhad. The responsible physician for assessment of imaging and clinical response and the patients will be blinded to the groups of patients.

Participants/Inclusion and exclusion criteria

The main inclusion criteria include patients with newly diagnosed invasive breast cancer that their diagnosis is confirmed by histologic evaluation and that are candidates for doxorubicin chemotherapy aged between 18-70 year old and in Karnofsky Performance Scale Index more than 70%. The main exclusion criteria include previous history of poor-control comorbidities, warfarin usage and anti-depression and anti-anxiety drugs usage.

Intervention groups

Patients will take two 15 milligram tablets per day In the crocin group, and two placebo tablets identical to crocin in the placebo group besides chemotherapy.

Main outcome variables

The primary endpoints of study are overall survival and progression free survival.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160706028815N4**
Registration date: **2018-04-29, 1397/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-29, 1397/02/09**
Update count: **0**

Registration date

2018-04-29, 1397/02/09

Registrant information

Name

Seyed Alireza Javadinia

Name of organization / entity

Department of Oncology, Omid Hospital, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of the effectiveness of addition of Crocin to doxorubicin containing chemotherapy regimen on survival of breast cancer patients

Public title
Effect of Crocin in treatment of breast cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Newly diagnosed invasive breast cancer The Karnofsky Performance Scale Index equal to or more than 70% doxorubicin containing chemotherapy regimen Unilateral breast cancer Age between 18 to 70 years old
Exclusion criteria:
chronic liver failure chronic kidney failure chronic heart failure previous history of hematologic malignancies History of taking Psychiatric drugs Warfarin usage Bipolar mood disorder Evidence of metastasis
Age
From **18 years** old to **70 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients with block randomization (1:1) will be allocated to treatment or placebo groups. First patients will be entered into one group based on sealed envelops and second patient will entered another group. Patients will be allocated to groups consecutively.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double blind study and the responsible physician for assessment of the clinical symptoms and imaging and patients are blind. An individual outside the study team will take responsibility for randomization to crocin and placebo.
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
Daneshgah Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138735499
Approval date
2017-11-01, 1396/08/10
Ethics committee reference number
IR.MUMS.fm.REC.1396.359

Health conditions studied

1

Description of health condition studied
Malignant neoplasm of breast
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Overall Survival
Timepoint
Every 3 months in the first year, every 4-6 months in the second year, every 6 months in third to fifth years and then annually
Method of measurement
visit

2

Description
Progression-free Survival
Timepoint
Every 3 months in the first year, every 4-6 months in the second year, every 6 months in third to fifth years and then annually
Method of measurement
Visit

Secondary outcomes

1

Description
Anemia
Timepoint
Before each session of chemotherapy every two to three weeks
Method of measurement
laboratory assessment of Complete blood count

2

Description
Neutropenia
Timepoint
Before each session of chemotherapy every two to three weeks
Method of measurement
laboratory assessment of Complete blood count

3

Description
Thrombocytopenia
Timepoint
Before each session of chemotherapy every two to three weeks
Method of measurement
laboratory assessment of Complete blood count

4

Description
Alopecia
Timepoint
Before each session of chemotherapy every two to three weeks
Method of measurement
physical examination

5

Description
Nausea
Timepoint
Before each session of chemotherapy every two to three weeks
Method of measurement
history taking

6

Description
vomiting
Timepoint
Before each session of chemotherapy every two to three weeks
Method of measurement
history taking

7

Description
Depression
Timepoint
In the first visit and then every four months
Method of measurement
Beck's Depression Inventory

8

Description
Anxiety
Timepoint
In the first visit and then every four months
Method of measurement
The Beck Anxiety Inventory

Intervention groups

1

Description
Intervention group: The patients will be requested to take two crocin tablets daily for four months (each tablet contain 15 milligram crocin). The crocin tabletes will be produced in the pharmacy faculty of Mashhad University of Medical Sciences from saffron. Although, the doxorubicin-containing chemotherapy regimen -using standard chemotherapy protocols in treatment of breast cancer- will be selected and will be calculated based on body surface area and will be prescribed every two-three weeks.
Category
Treatment - Drugs

2

Description
Control group: The patients will be requested to take two placebo tablets daily for four months. The crocin tabletes will be produced in the pharmacy faculty of Mashhad University of Medical Sciences. Although, the doxorubicin-containing chemotherapy regimen -using standard chemotherapy protocols in treatment of breast cancer- will be selected and will be calculated based on body surface area and will be prescribed every two-three weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Oncology Clinic of Omid Hospital
Full name of responsible person
Dr Roham Salek
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2

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Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Dr Mansooreh Dehghani
Position
Resident of radiooncology
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

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Seyed Alireza Javadinia

Position
Resident

Latest degree
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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