

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of therapeutic effect of crocin along with chemotherapy regimes in patients with breast cancer, A clinical trial

Protocol summary

Study aim

Evaluation of therapeutic effect of crocin along with chemotherapy regimes in patients with breast cancer, A clinical trial

Design

A double blind randomized controlled trial
Randomization, Method: Random allocation rule, Sample size: 100, Phase: 3

Settings and conduct

Study population are patients with metastatic breast cancer who were referred to Oncology centers in Mashhad. The treatment regime of participants will be according to the oncologist's opinion according to standard protocols. For intervention group taking Crocin pills will be also added to this regime. 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 pill. The daily dose of crocin will be 30 mg (two 15 mg tablets) for 24 weeks. The Sample size in this study is 100 patients (50 in each group).

Participants/Inclusion and exclusion criteria

-The participants studied will be patients with metastatic breast cancer. - Breast cancer patients with metastasis that is measurable. -Breast cancer patients who have not received any chemotherapy - Not having the history of any allergy to saffron or its products

Intervention groups

Intervention group: Crocin along with standard regime will be assigned to intervention group. The daily dose of crocin will be 30 mg during 24 weeks. Control group: The treatment regimen is with Folfiri, Folfox or Xelox and also placebo without Targeted therapy.

Main outcome variables

overall survival

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131017015044N3**

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

Soodabeh Shahidsales

Name of organization / entity

Cancer research center

Country

Iran (Islamic Republic of)

Phone

+98 51 1846 1518

Email address

shahidsaless@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 of therapeutic effect of crocin along with chemotherapy regimes in patients with breast cancer, A clinical trial

Public title

Therapeutic effect of crocin along with chemotherapy regimens in breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with metastatic breast cancer that is measurable Breast cancer patients who have not received any chemotherapy for metastasis

Exclusion criteria:

History of any allergy to saffron or its products

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: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule. This study with a sample size of 100 people, 50 balls for the placebo group and 50 balls for the intervention group are placed in a container and then the balls are randomly selected without replacement.

Blinding (investigator's opinion)

Double blinded

Blinding description

Sequentially numbered, sealed, opaque envelopes. A random sequence is created by random allocation rule. Then, based on the sample size, 100 envelopes with aluminum foil inside (to prevent "hot lighting") are prepared. Each entity in the random sequence is noted on a card and are replaced in numbered envelop. Finally, the envelopes are sealed and placed in boxes, respectively. The envelopes are respectively assigned to each participant so the participant's assigned group is 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

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2018-07-25, 1397/05/03

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.309

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

Overall survival

Timepoint

One year after the treatment is completed

Method of measurement

Patient follow-up

Secondary outcomes

1

Description

Progression-free survival

Timepoint

During treatment and after it every 3 months

Method of measurement

criteria of Response evaluation criteria in solid tumors

2

Description

Anemia

Timepoint

Before each session of monthly chemotherapy

Method of measurement

laboratory assessment of complete blood count

3

Description

Neutropenia

Timepoint

Before each session of monthly chemotherapy

Method of measurement

laboratory assessment of complete blood count

4

Description

Thrombocytopenia

Timepoint

Before each session of monthly chemotherapy

Method of measurement

laboratory assessment of complete blood count

5

Description

kidney function

Timepoint

Before each session of monthly chemotherapy

Method of measurement

laboratory assessment of BUN and creatinine

6

Description

liver function

Timepoint

Before each session of monthly chemotherapy

Method of measurement

laboratory assessment of SGOT and SGPT

Intervention groups

1

Description

Intervention group: Crocin along with standard regime will be assigned to intervention group. The daily dose of crocin will be 30 mg during 24 weeks.

Category

Treatment - Drugs

2

Description

Control group: The treatment regimen is with Folfiri, Folfox or Xelox and also placebo without Targeted therapy.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Soodabeh Shahidsales

Street address

Omid Hospital, Alandasht intersection, Koohsangi Street

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info@hospitalomid.com

Web page address

<http://omid.mums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences, Khorasan Razavi, Mashhad, Daneshgah Street

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presidentoffice@mums.ac.ir

Web page address

<https://www.mums.ac.ir/>

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
Soodabeh Shahidsales
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Omid Hospital, Alandasht intersection, Koohsangi
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

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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