

# 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

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

#### 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

#### 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)

##### Phone

+98 51 3802 2736

##### Email address

javadiniaa941@mums.ac.ir

##### 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 envelopes 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

##### **Street address**

Koohsangi Ave.

##### **City**

Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9176613775  
**Phone**  
+98 51 3842 6936  
**Email**  
Salekr@mums.ac.ir  
**Web page address**  
[http://research.mums.ac.ir/webdocument/load.action?webdocument\\_code=8000&masterCode=8000386](http://research.mums.ac.ir/webdocument/load.action?webdocument_code=8000&masterCode=8000386)

## 2

### Recruitment center

**Name of recruitment center**  
Oncology Clinic of Imam Reza Hospital  
**Full name of responsible person**  
Dr Roham Salek  
**Street address**  
Daneshgah Ave.  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9137913316  
**Phone**  
+98 51 3842 6936  
**Email**  
salekr@mums.ac.ir  
**Web page address**  
[http://research.mums.ac.ir/webdocument/load.action?webdocument\\_code=8000&masterCode=8000386](http://research.mums.ac.ir/webdocument/load.action?webdocument_code=8000&masterCode=8000386)

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Dr Mohsen Tafaghodi  
**Street address**  
Daneshgah Ave.  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9137913316  
**Phone**  
+98 51 3841 1538  
**Fax**  
+98 51 3843 0249  
**Email**  
tafaghodim@mums.ac.ir  
**Web page address**  
**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**  
Medical doctor  
**Other areas of specialty/work**  
Oncology  
**Street address**  
Koohsangi Ave.  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
917661377  
**Phone**  
+98 51 3842 6083  
**Fax**  
**Email**  
DehghaniM951@mums.ac.ir  
**Web page address**  
[http://research.mums.ac.ir/webdocument/load.action?webdocument\\_code=8000&masterCode=8013565](http://research.mums.ac.ir/webdocument/load.action?webdocument_code=8000&masterCode=8013565)

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Dr Roham Salek  
**Position**  
Radiooncologist  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Oncology  
**Street address**

Koohsangi Ave.  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
917661377  
**Phone**  
+98 51 3842 6083  
**Fax**  
**Email**  
DehghaniM951@mums.ac.ir  
**Web page address**  
[http://research.mums.ac.ir/webdocument/load.action?  
webdocument\\_code=8000&masterCode=8000386](http://research.mums.ac.ir/webdocument/load.action?webdocument_code=8000&masterCode=8000386)

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Seyed Alireza Javadinia  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Oncology  
**Street address**  
Omid Hospital, Koohsangi Avenue, Shariati square  
**City**  
Mashhad  
**Province**

Razavi Khorasan  
**Postal code**  
917661377  
**Phone**  
+98 51 3842 6936  
**Fax**  
**Email**  
javadiniaa941@mums.ac.ir  
**Web page address**  
[http://research.mums.ac.ir/webdocument/load.action?  
webdocument\\_code=8000&masterCode=8011136](http://research.mums.ac.ir/webdocument/load.action?webdocument_code=8000&masterCode=8011136)

## 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