# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Exploring the antitumor activity of curcumin in the treatment of breast-cancer patients

## Protocol summary

**Study aim**
Exploring the antitumor activity of curcumin in the treatment of breast-cancer patients in clinical trial setting

**Design**
A double blind randomized controlled trial
Randomization, Method: Random allocation rule, Sample size: 60, 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 Curcumin 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 Curcumin pill. The daily dose of Curcumin will be 80 mg for 24 weeks. The Sample size in this study is 60 patients (30 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 turmeric or its products

**Intervention groups**
Intervention group: Curcumin along with standard regime will be assigned to intervention group. The daily dose of Curcumin will be 80 mg during 24 weeks. Control group: The treatment regimen is with CAF, CMF or AC-TAXAN and also placebo without Targeted therapy.

**Main outcome variables**
overall survival

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20131017015044N4**
Registration date: **2020-01-23, 1398/11/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-23, 1398/11/03**
Update count: **0**

**Registration date**
2020-01-23, 1398/11/03

**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**
Exploring the antitumor activity of curcumin in the treatment of breast-cancer patients

**Public title**
Exploring the antitumor activity of curcumin 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 patients at the age of 25 to 70

**Exclusion criteria:**
History of any allergy to turmeric 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: **60**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Random allocation rule. This study with a sample size of 60 people, 30 balls for the placebo group and 30 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, 60 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 envelops 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**
2018-05-23, 1397/03/02

**Ethics committee reference number**
IR.MUMS.MEDICAL.REC.1398.369

## 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: Curcumin along with standard regime will be assigned to intervention group. The daily dose of crocin will be 80 mg during 24 weeks.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: The treatment regimen is with CMF, CAF or AC-TAXAN 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
**City**
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9176613775
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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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91388-13944
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+98 51 3841 2081
**Fax**
+98 51 3841 3006
**Email**
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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**
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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