

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Effects of Chicory and Fumitory products on hot flashes in breast cancer patients

#### Protocol summary

##### Study aim

Effects of Chicory and Fumitory products in hot flashes of women with breast cancer referred to cancer clinic of shahid modarres hospital 2019-2021

##### Design

Randomised clinical trial, Two arm parallel group design of 74 patients, Comparison between traditional medicine product and placebo

##### Settings and conduct

Firstly, we will evaluate the number and severity of hot flashes in first week of study as baseline and then, we will evaluate the number and severity of hot flashes in 4 weeks of intervention in two groups. Place of intervention: oncology clinic of shahid moddarres hospital

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women between 18 and 65 years; Breast cancer (stage 0-3); At least two hot flashes in 24 hours; At least 4 weeks have elapsed since treatment with estrogen suppressive hormone therapy (Tamoxifen, LHRH agonists, Aromatase inhibitors) and continued unchanged until the end of the intervention. And conditions of non-entry: Lack of informed consent to the plan; Life expectancy is less than 6 months; Having another cancer at the same time as breast cancer; The patient is undergoing chemotherapy, radiotherapy or surgery; Taking antidepressants in the last 4 weeks; Use of acupuncture and complementary medicine (hypnosis, psychotherapy) Use of Anxiolytic drug, Gabapentin, Pregabalin, Clonidine, Aspirin, Vitamin E, Omega 3 and high phytoestrogenic diet; Drug allergy to venlafaxine; Allergy to distilled of Chicory and Fumitory; BUN, CR is not in normal laboratory range; Liver enzymes AST and ALT are more than twice the normal laboratory range and Total Billirubin  $\geq 2$

##### Intervention groups

Group I: Chicory and Fumitory products recipients Group II: placebo recipient

##### Main outcome variables

Number of Hot flashes, Severity of hot flash

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210226050506N1**

Registration date: **2021-06-09, 1400/03/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-06-09, 1400/03/19**

Update count: **0**

##### Registration date

2021-06-09, 1400/03/19

##### Registrant information

##### Name

Nematollah Rostami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2243 9770

##### Email address

alireza.khosropanah1455@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-05, 1400/02/15

##### Expected recruitment end date

2021-07-21, 1400/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Effects of Chicory and Fumitory products on hot flashes in breast cancer patients

### Public title

Effects of Chicory and Fumitory products on hot flashes

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Women between 18 and 65 years Breast cancer (stage 0-3) Having at least two hot flashes in 24 hours At least 4 weeks have elapsed since treatment with estrogen suppressive hormone therapy (Tamoxifen, LHRH agonists, Aromatase inhibitors) Estrogen suppressive hormone therapy continued unchanged until the end of the intervention

#### Exclusion criteria:

Lack of informed consent to the plan Life expectancy is less than 6 months Having another cancer at the same time as breast cancer The patient is undergoing chemotherapy, radiotherapy or surgery Use of acupuncture and complementary medicine (hypnosis, psychotherapy) Taking antidepressants in the last 4 weeks Use of Anxiolytic drug, Gabapentin, Pregabalin, Clonidine, Aspirin, Vitamin E, Omega 3, Phytoestrogenic supplements Use of high phytoestrogenic diet Allergy to distilled of Chicory and Fumitory Kidney test (BUN,CR) is not in normal range Laboratory range Liver enzymes AST and ALT are more than twice the normal range Laboratory range and Total Bilirubin  $\geq 2$

### Age

From **18 years** old to **65 years** old

### Gender

Female

### Phase

2-3

### Groups that have been masked

- Participant
- Investigator

### Sample size

Target sample size: **64**

More than 1 sample in each individual

Number of samples in each individual: **32**

Randomization description(drug and placebo)

### Randomization (investigator's opinion)

Randomized

### Randomization description

In this study the restricted Randomization method of block randomization is used. Blocking is used to balance the number of samples assigned to each of the study groups. Randomization method was performed using balanced block randomization and in the form of 4 blocks using computer. Each drug is labeled with a number from 1 to 64. Patients were divided into two groups for the trial: the first group (32 people) intervention group or drug group and the second control group (32 people) placebo group. Both groups were equally divided in terms of characteristics and coordinated conditions. The

control group is assigned to "A" and the intervention group to "B", and then these two groups are divided into 6 blocks of 4: (1) AABB, (2) BBAA, (3) ABAB, (4) BABA, (5) AB BA, (6) BAAB .These blocks are randomly stacked together by a computer to form a chain of random groups (e.g. B B A A A B B A B B A B A A B B A B A A B ) Patients then enter these groups in the order of enrollment. For randomization, a randomization tool for random sequence software called Random allocation software is used. In addition to simple randomization, this software is also able to generate random sequences by block generation method. For concealment, we use allocation concealment, which is the method used to execute a random sequence on the study participants, so that the assigned group is not known before the individual is assigned. Drugs containing Chicory and Fumitory product or placebo were produced in the same shape and color and after coding were placed in sealed envelopes. Using opaque envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes) in which in this method each random sequence is recorded on a card and the cards are in the envelopes respectively. Are placed. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In this study, both chicory and fumitory products and placebo are made by the pharmacist in the laboratory and dumped and coded in similar batteries that only the pharmacist knows about the codes and in the same way it will be given for researchers and basis on randomization finally for participants both so the researcher and the participant are blinded.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Name of ethics committee Ethic committee of Shahid Beheshti University of Medical Sciences

##### Street address

Velenjak st. Shahid Chamran Highway school of medicin 3th floor

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۸۵۷۱۷۴۳

**Approval date**

2019-05-12, 1398/02/22

**Ethics committee reference number**

IR.SBMU.MSP.REC.1398.125

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

Breasts cancer

**ICD-10 code**

CD50

**ICD-10 code description**

Malignant neoplasm of breast

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

Number of hot flashes: This variable registered by patient based on defined daily in hot flashes daily registration form

**Timepoint**

At a specific time of night, it is recorded daily and continuously for one week before the intervention and four weeks during the intervention with drug or placebo

**Method of measurement**

Number of hot flashes average of frequency during a week according to based on Daily Hot flashes Diary

2**Description**

The severity of hot flashes in four levels , mild , moderate, severe and very severe, is recorded according to the definition registered by the patient in the Daily hot flashes Diary

**Timepoint**

At a specific time of night, it is recorded daily and continuously for one week before the intervention and four weeks during the intervention with drug or placebo

**Method of measurement**

Based on the weekly average daily hot flashes intensity based on the Daily hot flashes Diary

**Secondary outcomes**

empty

**Intervention groups**1**Description**

Intervention group1: Chicory and Fumitory products, obtained by at Institute of Medicinal Plants of shahid beheshti University, 5 ml per day until the end of the fourth weeks of intervention. In the preparation of this product, 20 grams of chicory seeds and 10 grams of aerial organs of fumitory are boiled and smoothed with 150 ml of water. 70 ml of this extract is combined with 35 grams of sugar and 20 ml of vinegar.

**Category**

Treatment - Drugs

2**Description**

Intervention group 2 : Placebo product, obtained by at Institute of Medicinal Plants of shahid beheshti University 5 ml per day until the end of intervention time. for produce this placebo, Oxymel syrup is used that combined with 1000 g sugar and 500 ml water and 250ml vinegar ,they are heated To achieve the desired consistency, Then the natural color appropriate to the drug is added to it.

**Category**

Placebo

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Oncology clinic Shahid Modarres Hospital

**Full name of responsible person**

Nematollah Rostami

**Street address**

Yadegare Imam Highway . Saadat Abad St

**City**

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**Email**

modarres@sbmu.ac.ir

**Web page address**<https://modarres.sbmu.ac.ir>**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

**Street address**

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

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msp@sbmu.ac.ir

**Web page address**

<http://research.sbmu.ac.ir>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nematollah Rostami

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nematollah Rostami

**Position**

Assistant profeesor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Alireza.khosropanah

**Position**

PositionMD.

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

Publishing results in form of a PhD thesis and an article indexing in ISI

### When the data will become available and for how long

After dissertation project thesis defence

### To whom data/document is available

Public

### Under which criteria data/document could be used

For research reasons

### From where data/document is obtainable

Shahid Beheshti University of Medical Sciences

### What processes are involved for a request to access data/document

Approving by responsible office

### Comments