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 distillated 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 ≥2

Intervention groups
Group 1: 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

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Nematollah Rostami

Name of organization / entity

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Iran (Islamic Republic of)

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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 distillated 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 ≥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 A B B A 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

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

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Postal code
۱۹۸۵۷۱۷۴۴۳
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 definied 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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
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Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Hematology

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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