Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of mixture of Distillated of Chicory and Fumitory compared with Venlafaxin on hot flashes in women with breast cancer

Protocol summary

Study aim

Effect of mixture of distillated of Chicory and Fumitory compared to venlafaxine in hot flashes of women with breast cancer referred to cancer clinic of Shohadaye Tajrish hospital in 2019-20

Design

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

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 Shohadaye Tajrish 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, Pregablin, 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: Mixture of distillated of Chicory and Fumitory recipients Group II: Venlafaxine recipient

Main outcome variables

Number of Hot flashes, Severity of hot flash

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190107042275N1**
Registration date: **2019-10-24, 1398/08/02**
Registration timing: **prospective**

Last update: **2019-10-24, 1398/08/02**
Update count: **0**

Registration date

2019-10-24, 1398/08/02

Registrant information

Name
Sina Moghtadaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8877 6027

Email address
sinamoghtadaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-01, 1398/08/10

Expected recruitment end date

2020-02-29, 1398/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effects of mixture of Distillated of Chicory and Fumitory compared with Venlafaxin on hot flashes in women with breast cancer

Public title
Effects of mixture of Distillated of Chicory and Fumitory on hot flash

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) and 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, Pregablin, Clonidine, Aspirin, Vitamin E, Omega 3, Phytoestrogenic supplements and high phytoestrogenic diet Drug allergy to venlafaxine Allergy to distillated of Chicory and Fumitory kidney test (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

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

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **74**
More than 1 sample in each individual
Number of samples in each individual: **37**

Randomization (investigator's opinion)
Randomized

Randomization description
Random sampling is performed by randomizer software on patients with inclusion criteria. The computer consists of numbers from zero to one if the random number is below 0.500 in the first group (distillated recipient) and if the number is above 0.500 enters in second group(Venlafaxin tablet recipient)

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
3th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2019-01-06, 1397/10/16

Ethics committee reference number
IR.SBMU.RETECH.REC.1397 .827

Health conditions studied

1

Description of health condition studied
Breast Cancer

ICD-10 code
C50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

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

Timepoint
Daily

Method of measurement
Daily Hot flashes Diary which is filled daily by the patient

2

Description
Severity of hot flashes: average of severity during a week according to based on Daily Hot flashes Diary

Timepoint
Daily

Method of measurement
Each hot flashes is recorded by the patient on a daily hot flashes diary record at 4 degrees of mild, moderate,

severe, and very severe.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Mixture of distillated of Chicory and Fumitory, obtained by steam distillation of chicory and fumitory leaves at Institute of Medicinal Plants of Shahid Beheshti University, 75 ml in the morning and 75 ml in the night untill the end of the fourth weeks of intervention.
Category
Treatment - Drugs

2

Description
Intervention group 2: Venlafaxine tablets of Abidi pharmacology 37.5 mg dialy for the first week and from the second week 75 mg venlafaxine tablets until the end of the fourth week of intervention.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Oncology clinic of Shohada Tajrish Hospital
Full name of responsible person
Sina Moghtadaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sponsor Vice chancellor for research, Shahid Beheshti University of Medical Sciences
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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
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Position
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Latest degree
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Person responsible for updating data

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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
Not applicable
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 PhD 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 officer
Comments