Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

investigating the effect of Viola odorata L. tablet on breast cancer-related fatigue: Pilot study

Protocol summary

Study aim
The aim of this study is determination of the effect of viola tablet on cancer fatigue in breast cancer patients.

Design
In this pilot study, which is performed in a simple, double-blind and randomized way using placebo, a maximum of 20 (10 people in each group) volunteer patients with breast cancer in the age range of 18-70 years who complain of fatigue, based on Inclusion criteria will be included in the study.

Settings and conduct
Before the intervention, a data collection form is completed for all patients referred to the radiotherapy-oncology section of Shohada-e-Tajrish Hospital. Fatigue severity is measured according to the criteria of visual analog fatigue scale, fatigue severity scale and cancer fatigue scale. Patients are devided to two groups randomly. Viola and placebo tablets will be packaged and coded in the same way. Patients' fatigue is measured at the beginning and end of the intervention (weeks of 0 and 4).

Participants/Inclusion and exclusion criteria
Women aged 18 to 70 years old Suffering from breast cancer During radiotherapy Hemoglobin at least 8 g /dl Hematocrit at least 30% SGOT level less than 3 times the upper limit of normal Bilirubin less than 2mg /dl Creatinine less than 2mg /dl normal TSH

Intervention groups
Intervention group: Group receiving viola tablets Control group: Placebo

Main outcome variables
Visual Analogue Fatigue Scale;Fatigue Severity Scale;The Cancer Fatigue Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220302054170N1**
Registration date: **2022-03-13, 1400/12/22**
Registration timing: **prospective**

Last update: **2022-03-13, 1400/12/22**
Update count: **0**

Registration date
2022-03-13, 1400/12/22

Registrant information

Name
Homa Hajimehdipoor

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8877 6168

Email address
hajimehd@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
investigating the effect of Viola odorata L. tablet on breast cancer-related fatigue: Pilot study

Public title
investigating the effect of Viola tablet on breast cancer-

related fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18 to 70 years old Suffering from breast cancer During radiotherapy Hemoglobin at least 8 g / dl Hematocrit at least 30% SGOT level less than 3 times the upper limit of normal Bilirubin less than 2mg / dl Creatinine less than 2mg / dl normal TSH

Exclusion criteria:

Heart disease with unstable conditions Debilitating lung disease History of asthma History of allergies to Viola or any of the excipients in tablets Uncontrolled pain Severe infection Serious accompanying disease

Age

From **18 years** old to **70 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

A table of random numbers will be created by rand Excel software. Before starting, we will determined the direction of selecting random numbers (for example from top to bottom). A series of random numbers will be selected from the table, and even numbers will be assigned to the control group and odd numbers to the intervention group. The codes will be then written on drug labels and kept secretly in an envelope. Containers containing coded drugs and placebo will be provided to the physician and research assistant. Patients start receiving from the smallest number of container to enter the plan. The first patient will be entered into the research will receive the intervention related to smallest code, and the last patient will receive the biggest code. Randomization unit: individual Randomization tool: Random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

The tablets code will be written to the file. The physician, assistant, and patient will not be aware of any tablet content. (double-blind).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences

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

City

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Province

Tehran

Postal code

19839-63113

Approval date

2022-02-20, 1400/12/01

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.1037

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

D05.9

ICD-10 code description

Unspecified type of carcinoma in situ of breast

Primary outcomes

1

Description

Visual Analogue Fatigue Scale

Timepoint

In weeks 0 and 4

Method of measurement

Questionnaire and Visual scale

2

Description

Fatigue Severity Scale

Timepoint

In weeks 0 and 4

Method of measurement

Questionnaire and Visual scale

3

Description

The Cancer Fatigue Scale

Timepoint

In weeks 0 and 4

Method of measurement

Questionnaire and Visual scale

Secondary outcomes

empty

Intervention groups

1

Description

The aqueous extract is prepared by boiling for 10 minutes using water in a ratio of 1:10. The extract prepared in the oven is dried at a temperature of 100 degrees and the resulting powder is used in the tablet formulation. To prepare the tablet, various types of medicinal excipients are used and pre-formulation studies are performed on them. The number of tablets used by patients after the tablet formulation will be determined depending on the amount of extract in each tablet. Since the effective dose in the animal study was 100 mg / kg and considering the formula: Equivalent human dose (mg / kg) = animal dose (mg / kg) × 0.162, the amount of extract for each person 60 kg was 972 mg. Per day is a dry extract of violet. Depending on the final formulation, there will be either two tablets per day (each containing 486 mg of extract) or three tablets per day (each containing 324 mg of extract).

Category

Treatment - Drugs

2

Description

Control group: The placebo will be made to look exactly like the original drug using the tablet's excipients.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiotherapy Center - Oncology of Shohada Tajrish Hospital

Full name of responsible person

Ghazale Heydari rad

Street address

Department of Radiotherapy, Shohadaye Tajrish Hospital , Tajrish Square,Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Grant name

Research Assistant of Shahid Beheshti University of Medical Sciences

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

Homa Hajimehdipoor

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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