

# 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 divided 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

##### **Street address**

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

##### **City**

Tehran

##### **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

##### City

Tehran

##### Province

Tehran

##### Postal code

19899 34148

##### Phone

+98 21 2271 8081

### Email

ghazalrad@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Homa Hajimehdipoor

##### Street address

No.8, shams Ali, Valiasr Ave.

##### City

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##### Province

Tehran

##### Postal code

1516745811

##### Phone

+98 21 8877 3521

##### Email

Hajimehd@sbmu.ac.ir

#### 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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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
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**Position**  
Professor  
**Latest degree**  
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## Person responsible for updating data

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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