

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### The effect of Plantago on the prevention of pulmonary complications of radiation therapy in patients with breast cancer

#### Protocol summary

##### Study aim

The purpose of this study was to evaluate the efficacy of Plantago syrup on the prevention of pulmonary radiotherapy in patients with breast cancer.

##### Design

Sixty patients with breast cancer participated in this study, who were randomly divided into two groups of intervention (n = 30) and control (n = 30). The intervention group received the syrup and the control group received the placebo.

##### Settings and conduct

This study is a double blind randomized clinical trial (participant and analyzer) in which a population of women with breast cancer is studied. The study is being conducted at Khansari Hospital in Arak. Participants are given Plantago syrups and placebo for three month. After three months spirometric parameters such as 1 FEV and FVC and 1 FVC / FEV ratio are measured.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Breast Cancer and Candidate Radiation Therapy 2. Ages between 17 and 65 years 3. Life expectancy of more than one year based on estimates of physician or medical team 4. Physical and mental ability to cooperate in filling out the questionnaire 5. Willingness to participate in the study 6. Absence of neutropenia, immune system weakness, myelosuction. Exclusion criteria: 1. Alcohol use, taking lung-affecting drugs such as antidepressants and opioids 2. History of connective tissue diseases such as Sjogren's, rheumatoid arthritis, diabetes; 3. History of dehydration-causing diseases such as chronic diarrhea, immunosuppressive diseases, myelosuppression

##### Intervention groups

Intervention group: Patients with breast cancer who are candidates for radiotherapy receiving syrup Control group: Patients with breast cancer are candidates for radiotherapy receiving placebo

##### Main outcome variables

Forced Vital Capacity :Forced Expiratory Volume in First

Second : Forced Vital Capacity (FVC) Ratio to Forced Expiratory Volume in First Second (FEV1)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180617040114N2**

Registration date: **2019-11-09, 1398/08/18**

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

Last update: **2019-11-09, 1398/08/18**

Update count: **0**

##### Registration date

2019-11-09, 1398/08/18

##### Registrant information

##### Name

jamal Amri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3502

##### Email address

jamal.amri71@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-11, 1398/07/19

##### Expected recruitment end date

2020-01-09, 1398/10/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

The effect of Plantago on the prevention of pulmonary complications of radiation therapy in patients with breast cancer

## Public title

Effect of Plantago on the of pulmonary complications of radiation therapy

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Breast Cancer and Candidate Radiation Therapy Ages between 17 and 65 years Life expectancy of more than one year based on estimates of physician or medical team Physical and mental ability to cooperate in filling out the questionnaire

### Exclusion criteria:

People with liver and kidney disease. People who have a history of allergy to herbal medicines.

## Age

From **17 years** old to **65 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The block randomization method with 4, 6 and 8 block sizes will be used to assign people to the two groups. Concealment will also be observed by using this method. In this way, each individual is assigned a unique code and is attached to drug packages that will help the blind process.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, the patient and the analyzer are blinded. Patients are not aware of the contents of the syrup glass and are similar in appearance to the syrup glass. And the analyzer is not aware of the data obtained.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Next to Amir al-Momenin Hospital, Bsij Square, Sardasht, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3848176341

#### Approval date

2019-07-23, 1398/05/01

#### Ethics committee reference number

IR.ARAKMU.REC.1398.078

## 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

Forced Vital Capacity (FVC)

#### Timepoint

Before intervention and three months after intervention

#### Method of measurement

Spirometry

### 2

#### Description

Forced Expiratory Volume in the second period (FEV1)

#### Timepoint

Before intervention and three months after intervention

#### Method of measurement

Spirometry

### 3

#### Description

Forced Vital Capacity (FVC) Ratio to Forced Expiratory Volume in the second period (FEV1)

#### Timepoint

Before intervention and three months after intervention

#### Method of measurement

Spirometry

## Secondary outcomes

### 1

#### Description

Phlegm and mucus in the throat

#### Timepoint

Before intervention and three months after intervention

#### Method of measurement

Aspiration

### 2

#### Description

Score of quality life

#### Timepoint

Before intervention and three months after intervention

#### Method of measurement

Quality of Life Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: This group includes 30 patients with breast cancer who are candidates for radiotherapy. This group receives the Plantago syrup for three months with treatment

#### Category

Prevention

### 2

#### Description

Control group: This group includes 30 patients with breast cancer who are candidates for radiotherapy. This group received placebo for three months with treatment

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah khansari hospital

##### Full name of responsible person

Seyed Amir Hossein Latifi

##### Street address

Daneshgah Street, Arak

##### City

Arak

##### Province

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##### Postal code

۳۸۱۹۶۹۳۳۴۰

##### Phone

+98 86 3313 6055

##### Fax

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Alireza Kamali

##### Street address

Next to Amir al-Momenin Hospital, Basij Square, Sardasht, Arak

##### City

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##### Province

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##### Postal code

3848176341

##### Phone

+98 86 3417 3645

##### Email

TCMR.2016@GMAIL.COM

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Vice chancellor for research, Arak 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

Arak University of Medical Sciences

##### Full name of responsible person

Seyed Amir Hossein Latifi

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Traditional Medicine

##### Street address

Next to Amir al-Momenin Hospital, Basij Square, Sardasht, Arak

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seiedalatifi@yahoo.com

## Person responsible for scientific inquiries

### Contact

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Arak University of Medical Sciences  
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Assistant Professor  
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## Person responsible for updating data

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**Email**  
seiedalatifi@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

No more information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable