

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

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Phone

+98 86 3313 6055

Fax**Email**

TCMR.2016@GMAIL.COM

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

Arak

Province

Markazi

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

City

Arak

Province
Markazi
Postal code
3848176341
Phone
+98 38 4817 6341
Email
seiedalatifi@yahoo.com

Person responsible for scientific 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
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3417 3645
Email
seiedalatifi@yahoo.com

Person responsible for updating data

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
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3417 3645
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