

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of Persian medicine based preparation from spaghula (*Plantago Ovata* Forsk) husk mucilage on prevention and treatment of oral mucositis in breast cancer patients receiving adriamycin

Protocol summary

Study aim

Determination the effect of spaghula husk mucilage on prevention of oral mucositis in breast cancer patients receiving adriamycin

Design

Double-blind randomized controlled clinical trial with placebo, with cross-over groups, sample size: 20 patients

Settings and conduct

breast cancer patients referring to Imam Ali Hospital Zahedan who are candidates for adriamycin and who have had mucositis in the first or second course of 4 courses of adriamycin, according to inclusion and exclusion criteria will enter the study. 20 patients will be enrolled in the study. Patients are randomly divided into two group of drug and placebo. both groups will be advised to adhere the oral hygiene instructions such as usage of soft toothbrush. At the start of the second or third course of adriamycin, the intervention will take place for 2 weeks, and after this two weeks, by the next dose of adriamycin.the place of the drug group will be replaced with the placebo group. In each intervention, relevant factors will be evaluated.

Participants/Inclusion and exclusion criteria

inclusion criteria: Breast cancer, Candidate for adriamycin, Age 17 to 65 years, Physical and mental ability to cooperate in filling in the questionnaire
exclusion criteria: Use of alcohol, medicines affecting the salivary glands, mouthwashes and artificial saliva and cigarettes during the study; receiving prior radiotherapy in the oral and oropharynx; a history of connective tissue diseases, diseases that cause recurrent aphthous stomatitis ; third and fourth degree mucositis; Receiving drugs that affect oral mucositis, such as prostaglandin,

Intervention groups

Drug: spaghula husk 500 milligram+3 drop vinegar in 30 milliliter water 3 times a day Placebo:

(maltodextrin400mg+carbomer 80 mg+ Cinnamon20 mg) +3 drop triethanolamine in 30 ml water 3 times a day

Main outcome variables

Mucositis intensity, Intensity of pain, Quality of Life, Dry mouth

General information

Reason for update

Announcement of termination of patients recruitment

Acronym

IRCT registration information

IRCT registration number: **IRCT20180923041093N1**

Registration date: **2018-12-02, 1397/09/11**

Registration timing: **prospective**

Last update: **2020-04-20, 1399/02/01**

Update count: **2**

Registration date

2018-12-02, 1397/09/11

Registrant information

Name

Fatemeh sadat Hasheminasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5333 8547

Email address

hashemifa67@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

2018-12-18, 1397/09/27

Actual recruitment end date

2019-03-13, 1397/12/22

Trial completion date

2019-03-27, 1398/01/07

Scientific title

Evaluation of the effect of Persian medicine based preparation from spaghula (Plantago Ovata Forsk) husk mucilage on prevention and treatment of oral mucositis in breast cancer patients receiving adriamycin

Public title

Effect of spaghula husk mucilage on prevention of chemotherapy-induced mucositis

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Breast cancer Candidate for adriamycin mucositis in screening course Remaining two courses of adriamycin with two weeks interval Age between 17 and 65 years Life expectancy for more than a year based on physician or team estimates Physical and mental ability to cooperate in filling in the questionnaire The desire to participate in the study

Exclusion criteria:

Use alcohol Use of drugs that affect salivary glands such as antipsychotics, opioids, antihypertensives, antihistamine, diuretics Use of mouthwashes and artificial saliva and cigarettes Receiving Early Radiation in mouth or oropharynx The history of connective tissue diseases, such as Sjogren, rheumatoid arthritis, lupus Liver and kidney disease Major Depression Diseases that affect salivary glands such as diabetes Diseases that induce dehydration such as chronic diarrhea Diseases of the immune system Recurrent aphthous stomatitis Receiving Lithium or Levothyroxine for interference with spaghula

AgeFrom **17 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

each patients receives placebo for two weeks and then drug for two weeks (or conversely).

Actual sample size reached: **19**

More than 1 sample in each individual

Actual sample size in each individual: **2**

each patients receives placebo for two weeks and then drug for two weeks (or conversely).

Randomization (investigator's opinion)

Randomized

Randomization description

use of random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug and placebo will coded by a third person (A - B). Therefore, the patient, researchers and outcome evaluators do not know which patient is in the drug group and which patient is in the placebo group. After the completion of the sampling, the third person will offer the codes to the data analyzer.

Placebo

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman university of medical sciences

Street address

Beginning of Ibn Sina Street, Beginning of Jihad Blvd., Somayeh Road (Tahmasebad), Kerman

City

Kerman

Province

Kerman

Postal code

584-76175

Approval date

2018-09-30, 1397/07/08

Ethics committee reference number

IR.KMU.REC.1397.239

Health conditions studied**1****Description of health condition studied**

Adriamycin induced oral mucositis

ICD-10 code

K12.31

ICD-10 code description

Oral mucositis (ulcerative) due to antineoplastic therapy

Primary outcomes

1

Description

degree of oral mucositis according to WHO scale

Timepoint

Precisely before the intervention, 7 days after the start of intervention and 14 days after the start of intervention (the last day of the intervention)

Method of measurement

WHO scale for oral mucositis

2

Description

degree of pain due to oral mucositis

Timepoint

Precisely before the intervention, 7 days after the start of intervention and 14 days after the start of intervention (the last day of the intervention)

Method of measurement

Visual Analogue Scale

3

Description

quality of life

Timepoint

Precisely before the intervention, 7 days after the start of intervention and 14 days after the start of intervention (the last day of the intervention)

Method of measurement

OHIP-14 questionnaire

4

Description

xerostomia

Timepoint

Precisely before the intervention, 7 days after the start of intervention and 14 days after the start of intervention (the last day of the intervention)

Method of measurement

LENT-SOMA scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A mixture of (500 ml ispaghula husk and 3 drops of vinegar in 30 cc water) should be kept in the mouth for 1 minute then poured out, three times a day . For 14 days. The intervention begins from the start of the Adriamycin Course and continues until the next course begins.

Category

Treatment - Drugs

2

Description

Control group: placebo: A mixture of (400 mg maltodextrin + 80 mg carbomer +20 mg cinnamon +3 drops of triethanolamine in 30 cc water) should be kept in the mouth for 1 minute then poured out, three times a day . For 14 days. The intervention begins from the start of the Adriamycin Course and continues until the next course begins.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Teaching Hospital

Full name of responsible person

Seyed Mehdi Hashemi

Street address

Persian Gulf Expressway, Zahedan, Sistan and Baluchestan Province

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

0

Phone

+98 54 3329 5570

Email

avecina75483@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman university of medical sciences

Full name of responsible person

Abbas Pardakhti

Street address

Kerman university of medical sciences, Haft-Bagh Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3226 3855

Fax

+98 34 3226 3857

Email

abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Hasheminasab

Position

PhD student of Persian medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Faculty of Traditional Persian Medicine, Amir Kabir crossroad

City

Kerman

Province

Kerman

Postal code

7618843883

Phone

+98 34 3211 0860

Email

hashemifa67@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Mohammad Setayesh

Position

assistant professor of traditional Persian medicine

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Faculty of Traditional Persian Medicine, Amir Kabir

crossroad

City

Kerman

Province

Kerman

Postal code

7618843883

Phone

+98 34 3211 0860

Email

msetayeshmail@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Hasheminasab

Position

PhD student of traditional Persian medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Faculty of Traditional Persian Medicine, Amir Kabir crossroad

City

Kerman

Province

Kerman

Postal code

7618843883

Phone

+98 34 3211 0860

Email

hashemifa67@gmail.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be shared through a supplementary file after unidentified individuals.

When the data will become available and for how long

Start the access period from 6 months after printing results

To whom data/document is available

Researchers and other people can access data if they need it.

Under which criteria data/document could be used

For use in review articles, reprogramming and modeling can be used in other studies. In case of need, should be emailed to the programmer.

From where data/document is obtainable

Executor of plan or University

What processes are involved for a request to access data/document

Email the scheduler (Dr.Setayesh) ,he answers.

Comments

All information is available to others for the advancement of science.