Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 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
Age
From **17 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target 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 (Tahmasebabad), 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 proffesor 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

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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.