Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Salvadora persica stick (miswak) and Persica mouthwash solution on the severity of stomatitis and its pain in patients undergoing chemotherapy for Breast Cancer.

Protocol summary

Study aim
Comparison of the effect of toothbrush stick and Persica mouthwash solution on the severity of stomatitis and its pain in patients undergoing chemotherapy in breast cancer

Design
Double-blind randomized clinical trial, phase 2 on 75 patients. A random number table will be used for randomization

Settings and conduct
75 patients with breast cancer select via convenience method and randomly assign into three groups of toothbrush stick, Persica mouthwash and control. Patients' oral health status assess before, 7 and 14 days after the start of treatment for the severity of stomatitis and pain by a trained coworker who is unaware of patients groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnose breast cancer, The first session of chemotherapy, Age 20-60 years, Having natural teeth, no oral malformations, and oral mucousal health, Consent to participate in the study Ineligible criteria: Use of analgesics, antibiotics, and other mouthwash solutions, Drug addiction and smoking, History of sensitivity to specific substance, Underlying diseases, receiving treatment simultaneously (radiotherapy)

Intervention groups
Intervention group 1: Using toothbrush stick three times a day (after each meal) on the inner, outer and chewing surfaces of the teeth for 5 minutes with forward and backward movements Intervention group 2: Using soft toothbrush and toothpaste for children three times a day (after each meal) followed by using Persica mouthwash for 30-60 seconds Control group: receiving routine care in the ward

Main outcome variables
Decrease severity and pain due to stomatitis

General information

Reason for update
Change and modification of the statistical community

Acronym

IRCT registration information
IRCT registration number: **IRCT20171002036505N2**
Registration date: **2021-04-26, 1400/02/06**
Registration timing: **prospective**

Last update: **2021-10-17, 1400/07/25**
Update count: **1**

Registration date
2021-04-26, 1400/02/06

Registrant information

Name
Zahra Pishkar Mofrad

Name of organization / entity
Zahedan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-05-21, 1401/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Salvadora persica stick (miswak) and Persica mouthwash solution on the severity of stomatitis and its pain in patients undergoing chemotherapy for Breast Cancer.

Public title
The effect of Salvadora persica stick (miswak) and Persica mouthwash solution on the severity and pain of stomatitis in patients undergoing chemotherapy.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
The definitive diagnosis of breast cancer The first session of chemotherapy Age range of 20-60 years Having natural teeth, no oral malformations, and oral mucosal health at the time of study Consent to participate in the study
Exclusion criteria:
Use of analgesics, antibiotics, and other mouthwash solution Addiction to drugs and smoking History of sensitivity to specific substance, allergic rhinitis, and dermatitis Underlying diseases (diabetes mellitus, hepatitis, liver and kidney disorders, and gastrointestinal diseases) Concomitant treatments such as radiation therapy
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who meet the inclusion criteria will be by random allocation method and using dice (Roll of a dice),will be assigned to three groups: toothbrush stick (25 people), Persica mouthwash (25 people) and control (25 people). Numbers 1 and 2 will be considered for the toothbrush stick group, numbers 3 and 4 will be considered for the Persica mouthwash group and numbers 5 and 6 will be considered for the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
1. The person who evaluates the mouth of the patients participating in the study is blind. Thus, the mouth evaluation of patients in terms of incidence and severity of stomatitis will be performed by a study colleague who is unaware of the patient group, and the result is coded in the checklist of each group (patients in the Salvadora persica stick intervention group). Will register with M code and Persica mouthwash solution group with P code and control group with C code. 2. The statistical consultant in charge of data analysis will be unaware of the intervention groups; The data will be entered by the researcher with codes M, P, C in SPSS and will be provided to the statistical consultant for analysis.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Campus of Medical Sciences, Dr. Hesabi Squ
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816913396
Approval date
2021-02-01, 1399/11/13
Ethics committee reference number
IR.ZAUMS.REC.1399.535

Health conditions studied

1

Description of health condition studied
stomatitis
ICD-10 code
K12
ICD-10 code description
ICD-10-CM Code K12 - Stomatitis and related lesions

2

Description of health condition studied
breast cancer
ICD-10 code
C50
ICD-10 code description
ICD-10-CM Code C50-Malignant neoplasm of breast

Primary outcomes

1

Description
stomatitis
Timepoint
7 and 14 days after the intervention
Method of measurement
World Health Organization (WHO) scale for oral mucositis

2

Description
Pain
Timepoint
7 and 14 days after the intervention
Method of measurement
Visual Analog Scale for Pain

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: After moistening the toothbrush stick with cold boiled water for 15 minutes, patients move the toothbrush stick like a normal toothbrush, on the inner, outer and chewing surfaces of the teeth for 5 minutes three times a day (after each meal) and refrain from eating for up to an hour.
Category
Prevention

2

Description
Intervention group 2: Patients will brush their teeth three times a day (after each meal) with a soft toothbrush and toothpaste for children, followed by using 15 drops of Persica mouthwash diluted with 15 cc teeth for half to one minute and taking it out and refraining from eating for an hour.
Category
Prevention

3

Description
Control group: Patients will not receive any intervention and will perform routine care.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Oncology wards of Khatam & Ali Ibn Abitaleb Hospitals in Zahedan
Full name of responsible person
Zahra Pishkar Mofrad
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Sponsors / Funding sources

1

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Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Zahra Pishkar Mofrad

Position
Instructor, faculty member

Latest degree
Master

Other areas of specialty/work
Nursery

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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