

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

Decrease severity and pain due to stomatitis

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

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

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 2481

Email address

pishkar@zaums.ac.ir

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

Street address

Campus of Medical Sciences, Dr. Hesabi Squ

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3337 2151

Email

pishkarz@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Normohammad Bakhshani

Street address

Campus of Medical Sciences, Dr. Hesabi Squ

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3337 2151

Fax

+98 54 3337 2116

Email

public@zaums.ac.ir

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

Moya.2471@gmail.com

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
Street address
Mashahir square.School of Nursing & Midwifery
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3344 2481
Email
pishkarz@gmail.com

Person responsible for scientific 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
Street address
میدان دکتر حسابی، پردیس علوم پزشکی
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3337 2151
Email

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Mojtaba Yaghoubi Mohammadabad
Position
Master student of Intensive Care Nursing
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
میدان دکتر حسابی، پردیس علوم پزشکی
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3337 2151
Email
Moya.2471@gmail.com

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