

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial to assess the effectiveness of antiemetic and anti-halitosis topical peppermint cream and orally ingestible peppermint oxymel mouthwash in breast cancer patients during chemotherapy

Protocol summary

Study aim

Investigating the impact of topical peppermint cream and orally ingestible peppermint oxymel mouthwash on nausea and halitosis of breast cancer patients receiving chemotherapy

Design

A randomized one-blind phase 3 clinical trial on 225 patients, having control, and parallel groups. Randomization achieves by distinguishing participants into 6 blocks.

Settings and conduct

This study is to improve nausea and halitosis in patients with breast cancer. In addition to taking anti-nausea medications including Aprepitant and Dexamethasone, patients take two oral mouthwash drugs peppermint oxymel mouthwash and topical peppermint cream on days 1 to 6 of each course of chemotherapy. The research is carried out jointly in the trusted Motamed Cancer Institute and Emam Reza hospital. For data collection a questionnaire utilized, containing a tale in which patients rank their halitosis from 1-10; checking once per 2 weeks with the center. Furthermore, the vomiting and nausea questionnaire will be completed by the corresponding nurse. It is only possible to blind the researcher and analyst.

Participants/Inclusion and exclusion criteria

Stages 1 to 4 breast cancer patients that received chemotherapy.

Intervention groups

The control group receives anti-nausea drugs, one of the test groups receives ingestible peppermint oxymel mouthwash, and the other test group uses topical peppermint Cream in the form of topical on their forehead and behind ears, in addition to the control drugs.

Main outcome variables

Mouth halitosis; nausea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201219049763N1**

Registration date: **2021-06-08, 1400/03/18**

Registration timing: **prospective**

Last update: **2021-06-08, 1400/03/18**

Update count: **0**

Registration date

2021-06-08, 1400/03/18

Registrant information

Name

Alireza Madjid Ansari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8879 6208

Email address

majidansari@acecr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-20, 1400/03/30

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to assess the effectiveness of antiemetic and anti-halitosis topical peppermint cream and orally ingestible peppermint oxymel mouthwash in breast cancer patients during chemotherapy

Public title

Assessing the effectiveness of topical peppermint cream and orally ingestible peppermint oxymel mouthwash on halitosis and vomiting of breast cancer patients during chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

No history of nausea and vomiting for other reasons Full consciousness Literacy Complete satisfaction in participating in this project Breast cancer, ac4T4 chemotherapy regimen, taking anti-nausea and vomiting drugs Aprepitant and Dexamethasone No history of allergies Medicinal plants No history of respiratory diseases, asthma, diabetes and autoimmune diseases

Exclusion criteria:

Eliminate patients who use medications or treatments other than those prescribed during the study to reduce nausea and vomiting Patients who forget to use the product and mouthwash three or more times in a row

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **225**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by assigning the subjects under study to 6 blocks. In each block, individuals are randomly assigned to one of the groups using topical peppermint, peppermint oral mouthwash, and control in a ratio of 2-2-2. The order of random assignment of individuals to the study groups in each block is kept in sealed envelopes, and the individual who has nothing to do with measuring the outcomes is responsible for assigning individuals to different treatments.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the difference in the combination of the two drugs used, it is not possible to blind the participant and clinical care. Also, in order to follow the patients and evaluate the effectiveness and side effects of the drug, it is necessary to emphasize the adherence to the drug, so the evaluator cannot be blind. In this case, it is only possible to blind the researcher and analyst.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Motamed Cancer Institute

Street address

Gandhi South

City

Tehran

Province

Tehran

Postal code

1517964311

Approval date

2021-01-13, 1399/10/24

Ethics committee reference number

IR.ACECR.IBCRC.REC.1399.017

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

Breast cancer patients treated with chemotherapy drugs

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Nausea score in questionnaires

Timepoint

At the beginning of the study, every day based on the Daily questionnaire, every 14 days based on the Rhodes questionnaire

Method of measurement

Daily questionnaire and Rhodes questionnaire

2**Description**

Halitosis scores on questionnaires

Timepoint

At the beginning of the study, every day based on the Daily questionnaire, every 14 days based on the Rhodes questionnaire

Method of measurement

Daily questionnaire and Rhodes questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group one: In addition to taking the anti-nausea and antiemetic drugs Aprepitant and Dexamethasone, patients use mint serpentine mouthwash. Its ingredients are 5% water, 5% honey and 1% grape vinegar, to which 2% peppermint extract is added. How to use: 3 times a day, on days 1 to 6 of each course of chemotherapy. Each time, 2 tablespoons (equivalent to 10 ml) of mouthwash mixed with 6 tablespoons of water are mixed in the mouth and then swallowed.

Category

Treatment - Drugs

2

Description

Patients use topical peppermint cream in addition to the anti-nausea and antiemetic drugs Aprepitant and Dexamethasone. The ratio of its components is Cetostearyl alcohol 8g, Cetomacrogol 2g, poly ethylen glycol 6g, propylen glycol 6g, ethanol 10g, distilled water 60cc, peppermint essential oil 1cc. How to use: 3 times a day, on days 1 to 6 of each course of chemotherapy. Each time, rub 1 cm on the forehead and 0.5 cm on the back of each ear.

Category

Treatment - Drugs

3

Description

Control group: Patients taking only the usual anti-nausea and vomiting medications Aprepitant and Dexamethasone.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Motamed Cancer Institute

Full name of responsible person

Ramin Sarami Froshani

Street address

No.146, South Gandhi Street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1517964311

Phone

+98 21 8879 6308

Email

icbc@acecr.ac.ir

2

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Mohsen Rajae Nejad

Street address

West Fatemi Street, North Shahid Etemadzadeh Street

City

Tehran

Province

Tehran

Postal code

1411718546

Phone

+98 21 8609 6350

Email

icbc@acecr.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Ramin Sarami froshani

Street address

No.146, South Gandhi Street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1517964311

Phone

+98 21 8879 6208

Email

icbc@acecr.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranian academic center for education culture and research

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

Tehran

Postal code

1517964311

Phone

+98 21 8879 6208

Fax**Email**

majidansari@acecr.ac.ir

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

Iranian academic center for education culture and research

Full name of responsible person

Alireza Madjid Ansari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Integrative Oncology

Street address

No. 146 , South Gandhi Ave , Gandhi Square

City

Tehran

Province

Tehran

Postal code

1517964311

Phone

+98 21 8879 6208

Fax**Email**

majidansari@acecr.ac.ir

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

Iranian academic center for education culture and research

Full name of responsible person

Reyhane Ghadirian

Position

Expert

Latest degree

Master

Other areas of specialty/work

Cellular and Molecular Biology

Street address

No.146, South Gandhi Street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1517964311

Phone

+98 21 8879 6208

Email

reyhane_ghadirian@yahoo.com

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

Iranian academic center for education culture and research

Full name of responsible person

Alireza Madjid Ansari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Integrative Oncology

Street address

No. 146 , South Gandhi Ave , Gandhi Square

City

Tehran

Province**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