

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

A comparative study on the effect of sucking ice contained of pure water and ice contained of (mentha) mint extract on Xerostomia, nausea and vomiting during chemotherapy .

Protocol summary

Study aim

A comparative study on the effect of sucking ice contained of pure water and ice contained of (mentha) mint extract on Xerostomia, nausea and vomiting during chemotherapy

Design

This was a clinical trial. The participants consisted of 90 patients with breast cancer who convenient sampling was used and the selected individuals were randomly (lottery) assigned to control and intervention groups.

Settings and conduct

patients with breast cancer who visited the Emergency Oncology Ward of Omid Hospital at Mashhad for chemotherapy in 2016.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having a gag reflex, being able to swallow, written informed consent; Exclusion criteria: patients with kidney and digestive disease, restriction of fluid intake.

Intervention groups

Control group: Besides the routine treatment regimens, patients received 30 cc of water beginning from 5 minutes before the chemotherapy until the end. The first intervention group: Besides the routine treatment regimens, patients received 30 ice cubes, each containing 30 cc of water, provided in sterile packs beginning from 5 minutes before the chemotherapy until the end. The second intervention group: Besides the routine treatment regimens, patients received 30 small ice cubes (1 cm²), each containing 30 cc of water plus one drop of mint, provided in sterile packs beginning from 5 minutes before the chemotherapy until the end.

Main outcome variables

Nausea, Vomiting, Xerostomia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160606028293N2**

Registration date: **2019-07-30, 1398/05/08**

Registration timing: **retrospective**

Last update: **2019-07-30, 1398/05/08**

Update count: **0**

Registration date

2019-07-30, 1398/05/08

Registrant information

Name

mohammad haddadi

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4464 7241

Email address

haddadim92@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-11-11, 1394/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of sucking ice contained of pure water and ice contained of (mentha) mint extract on Xerostomia,nausea and vomiting during chemotherapy .

Public title

A comparative study on the effect of sucking ice contained of pure water and ice contained of (mentha) mint extract on Xerostomia,nausea and vomiting during chemotherapy

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with breast cancer under chemotherapy GAG reflex Ability to swallow Informed consent

Exclusion criteria:

Patients with gastrointestinal cancer limitation in drinking

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

the selected individuals were randomly (lottery) assigned to control and intervention groups

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

sabzevar University of Medical Sciences

Street address

Building Number two,Vice Chancellor for Education,Sabzevar University of Medical Sciences and Health services Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9618717653

Approval date

2015-07-15, 1394/04/24

Ethics committee reference number

IR.MEDSAB.REC.1394.53

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

Breast cancer

ICD-10 code

C50.8

ICD-10 code description

Overlapping lesion of breast

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

Xerostomia

Timepoint

Before and After Chemotherapy

Method of measurement

VAS

2**Description**

nausea

Timepoint

Before and After Chemotherapy

Method of measurement

vas

3**Description**

vomiting

Timepoint

Before and After Chemotherapy

Method of measurement

Number

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Besides the routine treatment regimens, patients received 30 cc of water beginning from 5

minutes before the chemotherapy until the end.

Category

Treatment - Drugs

2**Description**

The first intervention group: Besides the routine treatment regimens, patients received 30 ice cubes, each containing 30 cc of water, provided in sterile packs beginning from 5 minutes before the chemotherapy until the end.

Category

Treatment - Drugs

3**Description**

The second intervention group: Besides the routine treatment regimens, patients received 30 small ice cubes (1 cm 1), each containing 30 cc of water plus one drop of mint, provided in sterile packs beginning from 5 minutes before the chemotherapy until the end.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Omid Hospital

Full name of responsible person

Javad Ganjloo

Street address

Street koohsangi

City

Mashhad

Province

Razavi Khorasan

Postal code

9618717653

Email

haddadiM92@medsab.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice President of Research, Sabzevar University of Medical Sciences

Full name of responsible person

Javad Ganjloo

Street address

Building Number two, Vice Chancellor for Education, Sabzevar University of Medical Sciences and Health services

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Email

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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

Vice President of Research, Sabzevar 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**

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Haddadi

Position

Master of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Web page address**Person responsible for scientific inquiries****Contact**

Name of organization / entity

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Full name of responsible person

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Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Web page address**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

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

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Haddadi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery