Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity
Sabzevar University of Medical Sciences
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Mohammad Haddadi
Position
Instructor
Latest degree
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Nursery
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Person responsible for updating data

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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