

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The effect of spearmint-ginger capsule on incidence and severity of oral mucositis in patients with breast cancer undergoing chemotherapy in Tohid Medical Center, Sanandaj, 2018

Protocol summary

Study aim

The effect on the incidence and severity of oral mucositis ginger capsules Nna- patients undergoing chemotherapy for breast cancer patients in Tohid Medical Center.

Design

Randomized Clinical trial with control group; parallel groups, blinded, sample size 70

Settings and conduct

Clinical, triple blind clinical trials (chemotherapy patients; research collaborator and counselor) will be conducted at Tohid Hospital in Sanandaj.

Participants/Inclusion and exclusion criteria

text * Female and over 18 years. * At least the reading and writing literacy of the patient or one of the main members of the patient's family. * A definitive diagnosis of breast cancer by an oncologist and pathologist.. * History of at least one course of chemotherapy. * Do not receive the radiotherapy concurrent with chemotherapy. * Not taking therapeutic doses of warfarin, heparin and aspirin

Intervention groups

In the intervention group, a 500 mg ginger mixture containing 250 mg of ginger and 250 mg of peppermint powder will be given to chemotherapy patients. The intervention will take place about five hours before the chemotherapy completion. During this period, each day, two 500 mg ginger-mint capsules will be consumed at a time of 12 hours (a total of 1 g), preferably with an empty stomach. In the control group, a 500 mg starch capsule will be used

Main outcome variables

incidence of mucositis. severity of mucositis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180215038741N2**

Registration date: **2018-10-24, 1397/08/02**

Registration timing: **retrospective**

Last update: **2018-10-24, 1397/08/02**

Update count: **0**

Registration date

2018-10-24, 1397/08/02

Registrant information

Name

Havre Mawloudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3633 5014

Email address

Mawloudi.h@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-05, 1397/04/14

Expected recruitment end date

2018-10-06, 1397/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spearmint-ginger capsule on incidence and severity of oral mucositis in patients with breast cancer

undergoing chemotherapy in Tohid Medical Center, Sanandaj, 2018

Public title

The effect of spearmint-ginger capsule on incidence and severity of oral mucositis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

History of at least one course of chemotherapy Definitive diagnosis of breast cancer by clinical trials and an oncologist

Exclusion criteria:

Having a history of allergy to ginger or mint and taking them over the past week Metastasis to other organs of other body systems

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, by using the available sampling method and the random identification method, by using the referral list, the samples will first be selected based on entry criteria. Then, each eligible individuals will be allocated into control or intervention group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients undergoing chemotherapy; Research collaborators and counselors from the intervention and control group will be unaware.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

66617713446

Approval date

2018-06-10, 1397/03/20

Ethics committee reference number

IR.MUK.REC.1397/48

Health conditions studied

1

Description of health condition studied

Breast cancer patients

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Occurrence of mucositis, severity of mucositis

Timepoint

The first day of chemotherapy, five days after chemotherapy, ten days after chemotherapy, fourteen days after chemotherapy

Method of measurement

A questionnaire, an information recording form and Oral Health Index (OHI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: combination of spearmint _ Ginger capsules 500 mg containing 250 mg of ginger and 250 mg spearmint powder, every day two capsules will be given to chemotherapy patients within 12 hours. The intervention will begin one hour before the chemotherapy and will last for five days. Training will be given to patients in the early hours of chemotherapy. The capsules will be purchased by Barij Essen, Isfahan, with the standard code C200464 to the 1028 registration number.

Category

Treatment - Drugs

2

Description

Control group: Starch 500 mg capsules every day two capsules will be given to chemotherapy patients within 12 hours. The intervention will begin an hour before the chemotherapy and will last for five days. Training will be given to patients in the early hours of chemotherapy. The capsules will be purchased by Barij Essen, Isfahan, with the standard code C200464 to the 1028 registration number

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Hospital

Full name of responsible person

Havre Mawloudi

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj Sanandaj Kurdistan Iran, Islamic Republic Of

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3182 7464

Email

Mawloudi.h@muk.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Student Research Committee, Vice Chancellor for research and technology of Kurdistan University

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Pasdaran street, Sanandaj Sanandaj Kurdistan Iran, Islamic Republic Of

City

Sanandaj

Province

Kurdistan

Postal code

13446-66177

Phone

+98 87 3366 0092

Email

Mawloudi.h@muk.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Havre Mawloudi

Position

Senior Surgical Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj Sanandaj Kurdistan Iran, Islamic Republic Of

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3633 5014

Email

Mawloudi.h@muk.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Havre Mawloudi

Position

Senior Surgical Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj Sanandaj Kurdistan Iran, Islamic Republic Of

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3633 5014

Fax**Email**

Mawloudi.h@muk.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Havre Mawloudi

Position

Senior Surgical Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj sanandaj Kurdistan Iran

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3633 5014

Fax**Email**

Mawloudi.h@muk.ac.ir

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