Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 87 3633 5014

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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

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

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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

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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
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

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Person responsible for scientific inquiries

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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