Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of Honey- Ginger mouthwash on Oral Mucositis in Patients under Chemotherapy in Kashan Shahid Beheshti Hospital in 2020

Protocol summary

Study aim

Effect of Honey- Ginger mouthwash on Oral Mucositis

Design

This intervention is a double-blind clinical practice and will use clinical examination and study of patients' files (manual and electronic) to collect data. With the permission of Kashan University of Medical Sciences and the approval of the Ethics Committee, patients eligible to study n patients will be selected and assigned to two control and intervention groups (ginger mouthwash) with the help of block randomization model with 4 and 6 blocks.

Settings and conduct

After admission to the mouthwash intervention group, 600 mg (containing 300 mg of honey and 60 mg of ginger) It is given to the oral control group containing 600 mg of normal saline. Patients are asked to use 15 CC mouthwash every 2 minutes for 4 minutes at a dose (every 6 hours) and for 2 weeks (in the mouth and then in the mouth) and for half an hour after eating and drinking and avoid washing your mouth.

Participants/Inclusion and exclusion criteria

Having chemotherapy-induced mucositis; the patient must be at least 18 years old; patients have a definite diagnosis of cancer; no history of allergies; patients without systemic problems weaken the immune system. Output criteria: patients who received radiation therapy during the intervention; patients who received local anesthetic during the study; use another mouthwash during the study; patients who refused to quit smoking and did not eat spicy, acidic or spicy foods; patients with severe systemic problems.

Intervention groups

The control and intervention group are both chemotherapy patients who receive the ginger mouthwash intervention group and the 0.9% normal saline control group.

Main outcome variables

The severity of the pain; the severity of the mucositis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012438N32**
Registration date: **2020-08-23, 1399/06/02**
Registration timing: **prospective**

Last update: **2020-08-23, 1399/06/02**
Update count: **0**

Registration date

2020-08-23, 1399/06/02

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1555 0021

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taghizadeh_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-15, 1399/06/25

Expected recruitment end date

2020-12-15, 1399/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Honey- Ginger mouthwash on Oral Mucositis in Patients under Chemotherapy in Kashan Shahid Beheshti Hospital in 2020

Public title
Effect of Honey- Ginger mouthwash on Oral Mucositis in Patients under Chemotherapy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Having chemotherapy-induced mucositis Agree to participate in the study The patient must be at least 18 years old Patients have a definitive diagnosis of cancer (histological confirmation) Oral hygiene No history of allergies (asthma, allergic rhinitis) Patients without systemic problems weaken the immune system Absence of allergic diseases

Exclusion criteria:
Patients who received radiation therapy during the intervention Announcing the patient's non-cooperation at any stage of the project Patients who received local anesthetic during the study Use another mouthwash during the study Patients who refused to quit smoking and did not eat spicy, acidic or spicy foods. Patients with severe systemic problems (uncontrolled diabetes, advanced liver and kidney disease)

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
This intervention is a type of double-blind clinical practice and will use clinical examination and study of patients' files (manual and electronic) to collect data. With the permission of Kashan University of Medical Sciences and the approval of the ethics committee, 80 patients will be selected from the eligible patients and will be assigned to two control and intervention groups (ginger mouthwash) with the help of block randomization model with 4 and 6 blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
1) In pharmaceutical bottles, a certain amount of ginger is used to homogenize its taste with mouthwash. 2) Bottles used for placebo and mouthwash are dark in color to hide the contents of the bottles. 3) Bottles containing mouthwash and placebo are marked in the absence of the researcher

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of kashan University of Medical Sciences

Street address
Qutb Ravandi Boulevard, Kashan University of Medical Sciences

City
kashan

Province
Isfehan

Postal code
8715981151

Approval date
2020-05-19, 1399/02/30

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1399.011

Health conditions studied

1

Description of health condition studied
Oral Mucositis in Patients under Chemotherapy

ICD-10 code
K12.31

ICD-10 code description
Oral mucositis (ulcerative) due to antineoplastic therapy

Primary outcomes

1

Description
The severity of the pain

Timepoint
Before Intervention and day 7 and day14

Method of measurement
The VAS scale is given from zero to 10.

2

Description
The severity of the mucositis

Timepoint
Before Intervention and day 7 and day14

Method of measurement
Based on WHO mucositis evaluation criteria

Secondary outcomes

1

Description
Timepoint
Method of measurement

Intervention groups

1

Description
Intervention group: the oral intervention group receives 4% ginger extract and 7% honey obtained from the Biochemistry and Nutrition Research Center of Kashan University of Medical Sciences and rinses twice a day for 2 weeks, 3 times a day for 2 tablespoons for 1 minute each.
Category
Treatment - Drugs

2

Description
Control group: the oral intervention group receives 9% normal saline (Iran Injection and Pharmaceutical Products Company) and rinses twice a day for 2 weeks, 3 times a day for 2 tablespoons for 1 minute each.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital of Kashan
Full name of responsible person
Fateme Sadat Razavi
Street address
Shahid Beheshti Hospital, Ghotb Ravandi blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafshe
Street address
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Elahe Ghasem Zade Hosseini
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Diagnosis of oral diseases
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Only part of the data, such as pain severity, mucositis severity, age, sex, and type of disease, can be disseminated
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
It will only be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Analyzes related to promoting the scientific awareness of researchers and helping modern science are allowed
From where data/document is obtainable
fateme sadat razavi,09017336138,fatemee.razavii1994@gmail.com
What processes are involved for a request to access data/document
An applicant can send a request for a data file by e-mail. After reviewing the request, the data file will be sent to him/her after about three weeks would have passed from the date of the request
Comments