

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Email address

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

Isfahan

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

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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 scientific inquiries

Contact

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Person responsible for updating data

Contact

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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