

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Investigating the effect of 10% honey and 5% frankincense gel in the treatment of mucositis caused by radiotherapy in cancer patients: a parallel, randomized clinical trial

Protocol summary

Study aim

Investigation of Boswellia seratta honey gel in treatment of mucositis caused by radiotherapy in cancer patients

Design

This is a randomized clinical trial with a parallel design and a control group. This non-blinded study phases 2-3 will be conducted on 60 patients with mucositis induced by radiotherapy. Simple random is used for randomization, and the participants are assigned to two intervention and control groups.

Settings and conduct

This study will be conducted at the Shahid Fattahi Clinic of Kermanshah. After the initial screening and checking the inclusion criteria, if they meet the entry conditions and agree to participate in the study, the patients are randomly divided into two control and intervention groups, after receiving the relevant intervention, zero to seven days after the intervention, they are examined and evaluated and the results are reviewed and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Radiotherapy candidate patients in such a way that at least one-third of the oral mucosa is included; No history of head and neck radiotherapy. Exclusion criteria: A history of frankincense allergy; receiving concurrent chemotherapy regimen (other than cisplatin or cetuximab); Diabetes and history of hypoglycemia; Patients with recurrent infections; The presence of similar wounds in the genital area; Joint swelling and pain, eye problems such as pain, blurriness, and redness; Using other drugs to treat the pest.

Intervention groups

The intervention group will use topical gel containing frankincense and honey twice daily. The control group will use the placebo gel twice a day.

Main outcome variables

Pain intensity, sense of taste, ability to swallow solid and liquid substances, speech disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N197**

Registration date: **2023-02-24, 1401/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-24, 1401/12/05**

Update count: **0**

Registration date

2023-02-24, 1401/12/05

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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froughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-31, 1401/10/10

Expected recruitment end date

2023-07-01, 1402/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of 10% honey and 5% frankincense gel in the treatment of mucositis caused by radiotherapy in cancer patients: a parallel, randomized clinical trial

Public title

Efficacy of 10% honey and 5% frankincense gel in the treatment of mucositis caused by radiotherapy in cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent Radiotherapy candidate patients in such a way that at least one third of the oral mucosa is included No history of head and neck radiotherapy

Exclusion criteria:

A history of frankincense allergy receiving concurrent chemotherapy regimen (other than cisplatin or cetuximab) Patients with liver problems Diabetes and history of hypoglycemia Patients with recurrent infections The presence of similar wounds in the genital area Joint swelling and pain, eye problems such as pain, blurriness and redness Using other drugs to treat the pest

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method. Numbers 1-60 on the registration card, all codes are recorded on Card and stored in specific envelopes. Each of the generated codes is kept separately inside the envelope and the secretary gives one of these envelopes to the patient before the patient enters the doctor's room. Accordingly, the next patient code is not predictable. The doctor determines which treatments to perform based on the patient's code (If the number on the right side of the selected code is even, it will be in the intervention group, and if it is odd, it will be in the control group). Only the physician performing the intervention will be aware of the code assigned to the patient. After evaluating the outcome, based on the patient's name, the collected information will be linked to the assigned code.

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**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

IR.KUMS.REC.1401.328

Approval date

2022-11-01, 1401/08/10

Ethics committee reference number

IR.KUMS.REC.1401.328

Health conditions studied**1****Description of health condition studied**

Cancer

ICD-10 code

C80.0

ICD-10 code description

Disseminated malignant neoplasm, unspecified

Primary outcomes**1****Description**

Pain intensity

Timepoint

Zero, first, sixth and tenth days

Method of measurement

Using a visual pain scale

2**Description**

sense of taste

Timepoint

The zero and seventh days of study

Method of measurement

Using Patient Reported Outcome Measures (PROMS)

3

Description

Ability to swallow solid and liquid substances

Timepoint

The zero and seventh days of study

Method of measurement

Using Patient Reported Outcome Measures (PROMS)

4

Description

speech disorder

Timepoint

The zero and seventh days of study

Method of measurement

Using Patient Reported Outcome Measures (PROMS)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will use topical gel containing frankincense (10 percent) and honey twice daily for a week to ten days (the gel will be manufactured by Ariogen Sina Daru pharmaceutical company).

Category

Treatment - Drugs

2

Description

The control group will use the placebo gel (Gel containing carbomer does not contain active ingredient) twice a day for a week to ten days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Fatahi Clinic

Full name of responsible person

Dr. Seyed Shahram Miraghaei

Street address

The beginning of Si-Metri 2nd Street, Shahid Beheshti Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Cyrus Jalili

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Seyed Shahram Miraghaei

Position

Member of the academic staff of Kermanshah University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutical Sciences

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Person responsible for scientific inquiries

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Position

Member of the academic staff of Kermanshah University of Medical Sciences

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Person responsible for updating data

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Name of organization / entity

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available