Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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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 updating data

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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