Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Effect of local application of Glycyrrhiza glabra and eucalyptus extract for the prevention of chemoradiation Induced Oral Mucositis in head and neckmalignancies

Protocol summary

Study aim

Effect of local application of Glycyrrhiza glabra and eucalyptus extract for the prevention of chemoradiation Induced Oral Mucositis in head and neck malignancies

Design

This clinical trial was performed on 60 patients, divided into two groups of 30, including a control group and parallel groups. This study is blinded and simple randomization is used.

Settings and conduct

The field of work is clinical - internal. This study is performed in the Tohid Hospital in Sanandaj. The intervention group is given the solution containing Glycyrrhiza glabra and eucalyptus extract until the end of the course of radiotherapy. The control group is given the container containing the normal saline solution until the end of the course of radiotherapy,

Participants/Inclusion and exclusion criteria

Inclusion criteria:Head and neck carcinoma; Full awareness; Oral mucosal health Exclusion criteria: History of allergy to medicinal plants; High blood pressure; Diabetes; Autoimmune diseases; Cardiovascular disease; The presence of mucosal lesions in the mouth; Previous history of radiotherapy and chemotherapy; Chronic liver diseases; Non-use of drugs; alcohol; cigarettes

Intervention groups

Intervention group: The recipient of the solution containing Glycyrrhiza glabra and eucalyptus extract, Intervention until the end of the course of radiotherapy. Control group: The recipient of the container containing the normal saline solution, Intervention until the end of the course of radiotherapy

Main outcome variables

Incidence of severe mucositis (Grade 3≤); need for analgesics during treatment; time of onset of mucositis; duration of mucositis

General information

Reason for update

Given that the patient, evaluators, and statistical analyst were unaware of the group allocation, which is also mentioned in the blinding section, the present study was conducted in a triple-blind manner.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190415043279N4**
Registration date: **2020-06-14, 1399/03/25**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-06, 1404/07/14**
Update count: **1**

Registration date

2020-06-14, 1399/03/25

Registrant information

Name
Pezhman Sharifi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 87 3324 9435
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p.sharifi@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of local application of Glycyrrhiza glabra and eucalyptus extract for the prevention of chemoradiation Induced Oral Mucositis in head and neckmalignancies

Public title
Effect of local application of Glycyrrhiza glabra and eucalyptus extract for the prevention of Mucositis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Head and neck carcinoma Full awareness Oral mucosal health
Exclusion criteria:
History of allergy to medicinal plants High blood pressure Diabetes Autoimmune diseases Cardiovascular disease Neutropenia The presence of mucosal lesions in the mouth Previous history of radiotherapy and chemotherapy Chronic liver diseases Active collagen vascular disease Non-use of drugs; alcohol; cigarettes
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, according to a randomized list, is assigned by a person outside the study according to the corresponding codes in the sealed envelopes, then assigned to any disease that is included in the study. Medications are identical in appearance, packaging, color, and so on.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Container solutions and placebo were identical with respect to appearance and only differed in coding of the capsules. The treatment code of the intervention supplements was blinded for subjects, investigators and staff involved in the conduct of the study.
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
Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran
City
Sanandaj
Province
Kurdistan
Postal code
66177-13446
Approval date
2017-06-20, 1396/03/30
Ethics committee reference number
IR.MUK.REC.1396/75

Health conditions studied

1

Description of health condition studied
Oral Mucositis
ICD-10 code
K12
ICD-10 code description
Stomatitis and related lesions

Primary outcomes

1

Description
Incidence of severe mucositis (Grade 3≤)
Timepoint
The beginning of the intervention, every week continuously, the end of the intervention, one week after the end of the intervention
Method of measurement
Clinical examination by an oncologist and determination of mucositis grading using (NCI-CTCAE) version 4

Secondary outcomes

1

Description
Need for painkillers during treatment
Timepoint
During the course of treatment

Method of measurement
Check list

2

Description
The incidence of any degree of mucositis
Timepoint
During the course of treatment
Method of measurement
Examination by an oncologist and registration in the checklist

3

Description
Time of onset of mucositis
Timepoint
When mucositis begins
Method of measurement
Examination by an oncologist and registration in the checklist

4

Description
Duration of mucositis
Timepoint
Time from onset to resolution of mucositis
Method of measurement
Examination by an oncologist and registration in the checklist

Intervention groups

1

Description
Intervention group: The recipient of the solution containing Glycyrrhiza glabra and eucalyptus extract, It is recommended to use 20 cc of it as a gargle for 30 seconds three times a day. Intervention until the end of the course of radiochemotherapy, the solution is prepared by a phytochemical specialist in a specialized laboratory.
Category
Prevention

2

Description
Control group: The recipient of the container containing the normal saline solution, It is recommended to use 20 cc as a gargle for 30 seconds. Intervention until the end of the course of radiochemotherapy, the solution is prepared by a phytochemical specialist in a specialized laboratory.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Tohid Hospital
Full name of responsible person
Bayazid Ghaderi
Street address
Tohid Hospital, Geriashan Ave
City
Sanandaj
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Kurdistan
Postal code
6616812131
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+98 87 3366 4645
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bayazid.g@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Afshin Maleki
Street address
Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.
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maleki43@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
Bayazid Ghaderi

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Blood and oncology

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Person responsible for updating data

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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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable