

# 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 neck malignancies

#### 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 $\leq$ ); 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)

##### Phone

+98 87 3324 9435

##### Email address

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 neck malignancies

**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

**Province**

Kurdistan

**Postal code**

6616812131

**Phone**

+98 87 3366 4645

**Email**

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, Pasharan 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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Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for scientific 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**

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6617713466

**Phone**

## 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