

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The Effect of Glycyrrhiza glabra extract on oral mucositis of patients under head and neck radiotherapy.

#### Protocol summary

##### Summary

This is a double-blind randomized controlled clinical trial study. 37 patients with mean age 45 years under radiotherapy in oncology ward of Khoramabad Ashayer Shohada and cancer institute of Imam Khomeini hospital in October 2010, to last October, 2011 had been participated in this study. After receiving written informed consent; The examiner evaluated them at the end of second weeks of radiotherapy. Patients were randomly classified into 2 groups: intervention (19 patients) and control (18 patients). The bottles containing 100 cc aqueous Glycyrrhiza extract 50% or placebo was given to every patient and ask them to use 2 cc twice per day for 14 days after starting radiotherapy. The main objective is the effect of liquorice extract on oral mucositis and The secondary objective is the effectiveness on the intensity of burning mouth in cancerous patients under radiotherapy. Inclusion criteria: Patients should be at least 18 years old; There should be definite diagnosis of head and neck cancer for patients; Radiation therapy dose determined by patient's radiotherapist should be at least 50 Gy; Patient should have the ability of using extract before every radiotherapy session; At least 50% mouth cavity should be in ray field. Exclusion criteria: Patients who are now under radiotherapy and or have received every type of treatment for head and neck cancer in recent years. Patients with allergic history to glycyrrhiza. Patients who had every type of mouth problem for example active infection, wound and etc. Patient's announcement of not cooperating in every step of project.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201203012464N4**

Registration date: **2016-07-01, 1395/04/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-07-01, 1395/04/11

##### Registrant information

###### Name

Shamsolmolok Najafi

###### Name of organization / entity

Faculty of Dentistry, Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8833 0375

###### Email address

najafi\_sh@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences keshavarz street blv, Qods Ave-Central Organization of Tehran University of Medical Sciences - 4th Floor

##### Expected recruitment start date

2013-01-20, 1391/11/01

##### Expected recruitment end date

2014-02-20, 1392/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Glycyrrhiza glabra extract on oral mucositis of patients under head and neck radiotherapy.

##### Public title

The effect of aqueous extract of Glycyrrhiza glabra on

oral inflammation from radiotherapy .

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Patients should be at least 18 years old; There should be definite diagnosis of head and neck cancer for patients; Radiation therapy dose determined by patient's radiotherapist should be at least 50 Gy (the average dose that often cause mucositis); Patient should have the ability of using extract before every radiotherapy session; At least 50% mouth cavity should be in ray field (diagnosed by radiotherapy expert).

Exclusion criteria: Patients who are now under radiotherapy for head and neck cancer and or have received every type of treatment and ray therapy for head and neck cancer in recent year. Patients with allergic history to glycyrrhiza. Patients who may show complications to medicine. Patients who couldn't use aqueous glycyrrhiza extract in their mouth on the base of their verdict or their examiner's saying. Patients who had every type of mouth problem for example active infection, wound and etc. Before starting radiotherapy. Patient's announcement of not cooperating in every step of project.

## Age

From **18 years** old to **149 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **36**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Faculty of Dentistry, University of Medical Sciences,  
Kuy-e-Daneshgah, Ghods St, Enghelab Blvd, Tehran,  
Iran

##### City

Tehran

##### Postal code

##### Approval date

2013-10-22, 1392/07/30

##### Ethics committee reference number

130.1551.92.3

## Health conditions studied

### 1

#### Description of health condition studied

head and neck malignancecies

#### ICD-10 code

C00-C14

#### ICD-10 code description

Malignant neoplasms of lip, oral cavity and pharynx

### 2

#### Description of health condition studied

Mucositis

#### ICD-10 code

L55-L59

#### ICD-10 code description

Radiation-related disorders of the skin and subcutaneous tissue

## Primary outcomes

### 1

#### Description

burning mouth

#### Timepoint

The first day and at the end of 14

#### Method of measurement

visual scale

### 2

#### Description

Wound size

#### Timepoint

The first day and at the end of 14

#### Method of measurement

Scaled graph paper

## Secondary outcomes

### 1

#### Description

drug interactions with analgesic drugs of patients

#### Timepoint

1week

#### Method of measurement

visual scale

### 2

#### Description

Licorice sensitivity

**Timepoint**

14 days

**Method of measurement**

Observability and Question

**Intervention groups**

**1**

**Description**

The bottles containing 100 cc aqueous Glycyrrhiza extract 50% was given to every patient and ask them to use 2 cc twice per day for 14 days after starting radiotherapy.

**Category**

Treatment - Drugs

**2**

**Description**

The bottles containing 100 cc liquid as placebo was given to every patient and ask them to use 2 cc twice per day for 14 days after starting radiotherapy.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Emmam Khomini Hospital

**Full name of responsible person**

Dr Shamsolmolk Najafi

**Street address**

Emam khomini Hospital, Gharib St, Keshavarz Blvd, Tehran, Iran

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mrs zolfaghari

**Full name of responsible person**

Dr Shamsolmolok Najafi

**Street address**

Faculty of Dentistry, University of Medical Science, Kuy-e-Daneshgah, Ghods St, Enghelab Blvd, Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mrs zolfaghari

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tehtan University of Medical Siense

**Full name of responsible person**

Dr Shamsolmolok Najafi

**Position**

Professor of Faculty of Dentistry, Tehran University of Medical Sciences, Department of Oral Medicin

**Other areas of specialty/work**

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**Full name of responsible person**

samira hajheidary

**Position**

DDS, Postgraduate student of Periodontology

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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Student

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*