

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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

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Email address

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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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Tehran University of Medical Sciences

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samira hajheidary

Position

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