

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation of the effectiveness of licorice mucoadhesive film and triamcinolone acetonide mucoadhesive film on symptoms of head and neck radiotherapy-induced mucositis in comparison with placebo

Protocol summary

Study aim

Application of Licorice and/or Triamcinolone acetonide muco-adhesive films as complementary medication in addition to standard oral care in neck and head radiotherapy induced oral mucositis

Design

Clinical trial with control group, parallel intervention groups, double blinded, randomized, phase 3 on 90 patients, Simple Random Sampling and random digits table was used for randomization.

Settings and conduct

The site of research: radiation section of Omid hospital in Isfahan. Blinding process in this research: Double blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with radiotherapy induced oral mucositis; age above 18 years; non-pregnant women; patient willingness to remain in the study. Non-inclusion criteria: History of drug abuse; simultaneous with another drug; allergy or intolerance to corticosteroids; inability to provide informed consent; high blood pressure; active gastric ulcer; Liver disease; neural disease; Endocrine disorders or other significant systemic diseases that make it difficult to implement the protocols or test the results.

Intervention groups

Intervention group1: group of licorice mucoadhesive, with Aphthogel brand name, in which participants take the drug three times a day after meals and once before sleep on the upper lip mucosal surface during the research. Intervention group2: group of triamcinolone mucoadhesive in which participants take the drug three times a day after meals and once before sleep on the upper lip mucosal surface during the research. Control group : group of placebo mucoadhesive, in which participants take the drug three times a day after meals and once before sleep on the upper lip mucosal surface during the research.

Main outcome variables

Oral mucositis grade; Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200303046685N1**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **retrospective**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

Registration date

2020-06-29, 1399/04/09

Registrant information

Name

Fahimeh Pakravan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3436 8793

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-11, 1398/09/20

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of licorice mucoadhesive film and triamcinolone acetonide mucoadhesive film on symptoms of head and neck radiotherapy-induced mucositis in comparison with placebo

Public title
Effectiveness of licorice and triamcinolone acetonide muco-adhesive films on mucositis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with radiotherapy induced oral mucositis Age above 18 years Non-pregnant women Patient willingness to remain in the study
Exclusion criteria:
History of drug abuse that interferes with the treatment procedure in the researcher's point of view simultaneous treatment with another drug allergy or intolerance to corticosteroids inability to provide informed consent high blood pressure active gastric ulcer liver disease, neural disease Endocrine disorders or other significant systemic diseases that make it difficult to implement the protocols or test the results

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Among patients suffering from oral mucositis induced by head and neck radiotherapy who referred to Seyed-olshohada hospital in Isfahan, 90 patients who have been examined by supervisor and have met the eligibility criteria, will enter the study and a number will be assigned to every patient. Then they will be divided into two intervention groups and one control group using block randomization (block size=30) through the random allocation service software. For allocation concealment, sealed coded boxes with randomized sequence with the same size and weight will be used.

Blinding (investigator's opinion)
Double blinded

Blinding description
Both the participant and the investigator are not aware of the administered medication because of the similarity of the films In appearance, color and smell provided to the participants

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Department of oral medicine Faculty of Dentistry; Isfahan University of Medical Sciences; Hezarjarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-12-19, 1398/09/28

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.548

Health conditions studied

1

Description of health condition studied

oral mucositis

ICD-10 code

K12.33

ICD-10 code description

Oral mucositis (ulcerative) due to radiation

Primary outcomes

1

Description

Mucositis Grade

Timepoint

At the beginning of the study and at days 7,14 and 21

Method of measurement

WHO mucositis assessment scale

Secondary outcomes

1

Description

Oral pain

Timepoint

At the beginning of the study and at days 7,14 and 21

Method of measurement

VAS (visual analogue scale)

Intervention groups

1

Description

Intervention group 1: Licorice mucoadhesive film, with Aphthogel brand name, made by Dr Saniee Pharmaceutical Company, locally applied on upper lip mucosa, after each meal and once before sleep, for 15 to 20 minutes.

Category

Treatment - Drugs

2

Description

Intervention group 2: Triamcinilone acetonide mucoadhesive film, with 1mg active ingredient, made by Dr Saniee Pharmaceutical Company, locally applied on upper lip mucosa, after each meal and once before sleep, for 15 to 20 minutes.

Category

Treatment - Drugs

3

Description

Control group: placebo mucoadhesive film with the same formulation as other drugs used in the study but without licorice and triamcinolone, made by Dr Saniee Pharmaceutical Company, locally applied on upper lip mucosa, after each meal and once before sleep, for 15 to 20 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed Al-Shohada hospital in Isfahan

Full name of responsible person

Fahimeh Pakravan

Street address

Soffeh boulevard

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8117891389

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Fahimeh pakravan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Only information such as main consequence or the like can be shared.

When the data will become available and for how long

Access to the results immediately after publication

To whom data/document is available

Open access

Under which criteria data/document could be used

Access to data is possible only after formal permission from corresponding author

From where data/document is obtainable

Corresponding author

What processes are involved for a request to access data/document

Formal letter or email

Comments