Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 31 3436 8793

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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 refereed 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

Isfehan

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
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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
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Person responsible for updating data

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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