Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the Effectiveness of Mouthwash "Soluble Dexamethasone in AlMg Syrup" in Radiotherapy and Chemotherapy-induced Oral Mucositis in Cancer Patients

Protocol summary

Study aim

The main purpose of this study is to evaluate the efficacy of local dexamethasone on Radiotherapy and Chemotherapy-induced oral mucositis.

Design

Two arm parallel group randomised trial with postoperative care and outcome assessment

Settings and conduct

This study is conducted in Omid research treatment center of Isfahan. Patients are examined and selected during the days of admission to the hospital, and the evidence is recorded and they are followed in four weeks.

Participants/Inclusion and exclusion criteria

Eighty patients is enrolled in the study:40 patients in interval and 40 patients in control group.Eligibility criteria:People undergoing chemotherapy or radiotherapy for cancer;They have oral mucositis (grade 2 or 3) as a result of treatment complications; There are three to four weeks left in their treatment. Exclusion criteria: Patient dissatisfaction; Patient non-cooperation.

Intervention groups

group 1:Dexamethasone Mouthwash group, In order to keep Dexamethasone on the wounds, it was given to the patients as a solution in AlMg syrup(4 ampoules of Dexa in a bottle of syrup). The patients should rinse their mouths every 8 h, after meals,for 30s with 10 ml(A tablespoon) from mouthwash and avoid eating and drinking for half an hour. group 2:control group,There is no intervention in this group and during their treatment in the hospital, they are followed and monitored for their oral mucositis.

Main outcome variables

Grade of mucositis; Visual Analogue Scale number

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220528055004N1**
Registration date: **2022-07-21, 1401/04/30**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-21, 1401/04/30**
Update count: **0**

Registration date

2022-07-21, 1401/04/30

Registrant information

Name

mohammad reza salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3630 2913

Email address

salehi@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the Effectiveness of Mouthwash "Soluble Dexamethasone in AlMg Syrup" in Radiotherapy and Chemotherapy-induced Oral Mucositis in Cancer Patients

Public title
Effect of Dexamethasone Mouthwash in Oral Mucositis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
People undergoing Chemotherapy or Radiotherapy for Cancer They have Oral Mucositis as a Result of Treatment Complications There are three to four Weeks left in their Treatment

Exclusion criteria:
Patient dissatisfaction Patient non-cooperation

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple Randomization, Flip the Coin.Based on this, each patient will be placed in one of the two groups after a coin flip.In this way, if the result of flipping a coin is heads, they are included in the control group, and if it is tails they are included in the mouthwash group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not 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
No. 34 , Block c , Zayanderud building , In front of Najvan entrance , Sohrvardi square

City
Isfahan

Province
Isfehan

Postal code
٨١٧٥٧٩٣٩٤٠

Approval date
2022-05-16, 1401/02/26

Ethics committee reference number
IR.MUI.RESEARCH.REC.1401.092

Health conditions studied

1

Description of health condition studied
Oral mucositis

ICD-10 code
K12.31

ICD-10 code description
Oral mucositis (ulcerative) due to antineoplastic therapy

Primary outcomes

1

Description
Grade of mucositis

Timepoint
The beginning of the study(Before intervention),7,14and 21 days after the starting

Method of measurement
In-person examination and registration based on World Health Organization's mucositis grading scale and Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dexamethasone Mouthwash group, In order to keep Dexamethasone on the wounds, it was given to the patients as a solution in AlMg syrup(4 ampoules of Dexa in a bottle of syrup). The patients should rinse their mouths every 8 h, after meals,for 30s with 10 ml(A tablespoon) from mouthwash and avoid eating and drinking for half an hour

Category
Treatment - Other

2

Description
Control group:There is no intervention in this group and during their treatment in the hospital, they are followed and monitored for their oral mucositis

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Omid hospital
Full name of responsible person
Mehran Sharifi
Street address
Farshadi Alley, Khayam St
City
Isfahan
Province
Isfehan
Postal code
8184917534
Phone
+98 31 3235 0210
Email
omid@mui.ac.ir
Web page address
http://omid.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash Dastjerdi
Street address
No. 4; Isfahan University of Medical Sciences ; Hezar Jerib street
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Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8138
Email
research@mui.ac.ir
Web page address
http://research.mui.ac.ir/fa

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
Mohammad reza Salehi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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No. 10,Dorsa apartment, Mozhgan deadlock, Tabibe esfahani Ave
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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Person responsible for updating data

Contact

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Esfahan University of Medical Sciences

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data and study documentation, such as non-identifiable data and the outcome of interventions, work methods and ... are collected in the form of thesis.In Shahrivar 1401, this information will be presented during a lecture and then it sent to scientific journals for public use

When the data will become available and for how long
The beginning of the access period is from 1402

To whom data/document is available
This information will be accessible to all interested parties.

Under which criteria data/document could be used
1) In order to increase awareness and improve approaches related to treatment and prevention in the field of research 2)To be presented to medical centers and used in treatment protocols 3)For use in research studies

From where data/document is obtainable
1)Dentistry library of the Isfahan University of Medical Sciences, persian theses section, to the website: http://elib.mui.ac.ir/faces/search 2) Send email to: leily.er@gmail.com salehi@dnt.mui.ac.ir 3)Search in scientific databases

What processes are involved for a request to access data/document
Search title in the scientific databases and the said site or send email to the email addresses and request

Comments