

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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 Dexamethasone 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

Isfahan

## Postal code

8117579496

## 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, 14 and 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**

Isfahan

**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

**City**

Isfahan

**Province**

Isfahan

**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

**Street address**

No. 10,Dorsa apartment, Mozhgan deadlock, Tabibe  
esfahani Ave

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8175494055

**Phone**

+98 31 3630 2913

**Email**

salehi@dnt.mui.ac.ir

## Person responsible for scientific inquiries

### Contact

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Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad reza Salehi

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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](mailto:leily.er@gmail.com) [salehi@dnt.mui.ac.ir](mailto: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**