Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the therapeutic effect of formulated mouthwash containing dexamethasone and fluconazole on oral lichen planus

Protocol summary

Study aim
Determining the therapeutic effect of a formulated mouthwash containing dexamethasone and fluconazole on oral lichen planus

Design
A phase III randomized clinical trial study with a control group is designed for 70 patients. Randomization is performed using a computerized random number table.

Settings and conduct
This randomized clinical trial is being conducted at Mashhad Dental School. Randomization is done using the sealed envelope method. Random numbers are generated with the help of the Randomaize.com website. The printed sheets will be placed inside the envelope. The envelopes will be closed and . Based on the contents of the envelope, the individual will be assigned to the intervention or control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adults over 18 and under 65 years of age People who are prescribed mouthwash due to the number or extent of pathological lesions, as approved by a specialist, and the severity of the lesions is equal to two or more according to the Thongprsom criteria. Those who have informed consent to participate in the study exclusion criteria: Severe problems due to systemic diseases (more than two according to the ASA classification). People who are unable to rinse their mouth with topical corticosteroids due to systemic or medication reasons. People who have severe dysplasia based on the pathology results People who, for whatever reason, do not wish to continue participating in the project. People who have allergies to the drug or a history of allergies to other components of the formulation. Topical and systemic use of corticosteroid medications in the last 3 weeks Pregnant and breastfeeding women Immunocompromised patients

Intervention groups
5 ml of a mouthwash formulated with dexamethasone 0.1 mg/ml + fluconazole 2 mg/ml, 3 times a day for 3 weeks

Main outcome variables
Severity of oral lichen planus lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250715066509N1**
Registration date: **2025-08-18, 1404/05/27**
Registration timing: **prospective**

Last update: **2025-08-18, 1404/05/27**
Update count: **0**

Registration date
2025-08-18, 1404/05/27

Registrant information

Name
Ehsan Jannat Abadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3883 2300

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jannatabadie4031@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-23, 1404/07/01

Expected recruitment end date
2026-06-21, 1405/03/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the therapeutic effect of formulated mouthwash containing dexamethasone and fluconazole on oral lichen planus

Public title

Investigating the effect of dexamethasone and fluconazole mouthwash on oral lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults over 18 and under 65 years of age People who are prescribed mouthwash due to the number or extent of pathological lesions, as approved by a specialist, and the severity of the lesions is equal to two or more according to the Thongprsom criteria. Those who have informed consent to participate in the study

Exclusion criteria:

Severe problems due to systemic diseases (more than two according to the ASA classification). People who are unable to rinse their mouth with topical corticosteroids due to systemic or medication reasons. People who have severe dysplasia based on the pathology results People who, for whatever reason, do not wish to continue participating in the project. People who have allergies to the drug or a history of allergies to other components of the formulation. Topical and systemic use of corticosteroid medications in the last 3 weeks Pregnant and breastfeeding women Immunocompromised patients

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Sealed envelope Sealed envelope method: The envelopes are prepared and printed by a member of the research team and random numbers are generated with the help of the website Randomaize.com. The printed sheets will be placed inside the envelope. The envelopes will be closed and their contents will not be visible from the outside. Then, initially, the purpose of the study is explained to the person who meets the conditions for entering the study and, if desired, they sign the informed consent form and take an envelope. Then, it is opened and based on the contents of the envelope, the person is entered into the intervention or control 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

Mashhad University of Medical Sciences- Research Ethics Committee

Street address

Mashhad Dental School, Azadi Square, Vakilabad Blvd

City

mashhad

Province

Razavi Khorasan

Postal code

911735984

Approval date

2025-06-11, 1404/03/21

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1404.037

Health conditions studied

1

Description of health condition studied

Oral lichenplanus

ICD-10 code

L43

ICD-10 code description

Diseases of the skin and subcutaneous tissue, Papulosquamous disorders

Primary outcomes

1

Description

Severity of oral lichen planus lesions

Timepoint

At the beginning of the study /1 week/2 weeks/3 weeks

Method of measurement

Thongprosam

2

Description

Pain and burning

Timepoint

At the beginning of the study /1 week/2 weeks/3 weeks

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
Treatment Satisfaction
Timepoint
End of the third week
Method of measurement
Treatment Satisfaction Questionnaire for Medication-9 (TSQM-9)

Intervention groups

1

Description
5 ml of a mouthwash formulated with dexamethasone 0.1 mg/ml + fluconazole 2 mg/ml, 3 times a day for 3 weeks
Category
Treatment - Drugs

2

Description
Control group: Mix a 0.5 mg tablet with 30 drops of nystatin 100,000 units and rinse 3 times a day for 3 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral and maxillofacial Diseases Department of Mashhad Dental School
Full name of responsible person
Dr. Atessa Pakfetrat
Street address
Department of Oral Medicine, School of Dentistry, Mashhad University of Medical Sciences, Vakilabad Blv
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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Mashhad University of Medical Sciences, Daneshgah St.
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Ehsan Jannatabadi
Position
Resident
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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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
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Some data including demographic properties, signs and symptoms

When the data will become available and for how long
11 months after publication

To whom data/document is available
academic researchers

Under which criteria data/document could be used
It is permitted to use the data in other studies with reference.

From where data/document is obtainable
Dr Atessa Pakfetrat e-mail: pakfetrata@mums.ac.ir

What processes are involved for a request to access data/document
Sending email to authors.

Comments