Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of two types of corticosteroid mouthwashes, Betamethasone and Dexamethasone, in the treatment of patients with aphthous stomatitis and lichen planus

Protocol summary

Study aim

Comparison of Two Corticosteroid Mouthwashes, Betamethasone and Dexamethasone, in the Treatment of Patients with Aphthous Stomatitis and Oral Lichen Planus

Design

In the second intervention group, a combination of 6 vials of dexamethasone ampoules, nystatin drops (100,000 units), aluminum hydroxide syrup (40 mg), and diphenhydramine syrup (160 mg) was prepared. Patients then used the dexamethasone mouthwash three times a day for 2 minutes each time, over a period of 14 days.

Settings and conduct

This double-blind study will be conducted at the Dental Clinic of the Faculty of Dentistry in Isfahan. In this double-blind study, patients were informed about their participation, while both the researchers and participants were kept blinded to group allocation. To achieve this, identical unlabeled bottles were prepared and assigned to patients using confidential coding. Patients were instructed not to eat or drink for up to 30 minutes after using the mouthwash.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Informed consent; Aged 18 years and older; Clinical and pathological diagnosis of oral aphthous stomatitis or lichen planus; Appropriate general health Exclusion criteria:Receipt of topical or systemic corticosteroids within the past three months; Known hypersensitivity to betamethasone or dexamethasone; Presence of severe or impactful systemic and underlying diseases; History of oral fungal infections pregnancy or breastfeeding

Intervention groups

In the first intervention group, a combination of 6 vials of betamethasone ampoules, nystatin drops (100,000 units), aluminum hydroxide syrup (40 mg), and diphenhydramine syrup (160 mg) was prepared. Patients then used the betamethasone mouthwash three times a day for 2 minutes each time, over a period of 14 days.

Main outcome variables

Allergy and oral thrush; Dry mouth; Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N282**
Registration date: **2026-07-31, 1405/05/09**
Registration timing: **prospective**

Last update: **2026-07-31, 1405/05/09**
Update count: **0**

Registration date

2026-07-31, 1405/05/09

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 83 1821 4653
Email address
fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-16, 1405/05/25

Expected recruitment end date

2026-09-16, 1405/06/25

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of two types of corticosteroid mouthwashes, Betamethasone and Dexamethasone, in the treatment of patients with aphthous stomatitis and lichen planus

Public title
Comparison of corticosteroid mouthwashes, Betamethasone and Dexamethasone, in the treatment of patients with aphthous stomatitis and lichen planus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent Aged 18 years and older Clinical and pathological diagnosis of oral aphthous stomatitis or lichen planus Appropriate general health
Exclusion criteria:
Receipt of topical or systemic corticosteroids within the past three months Known hypersensitivity to betamethasone or dexamethasone Presence of severe or impactful systemic and underlying diseases (e.g., uncontrolled diabetes, renal failure, active cancer Use of corticosteroids and immunosuppressive agents History of oral fungal infections pregnancy or breastfeeding Tobacco use (cigarettes or hookah)
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization using the blocking method with blocks in sizes 6 and 9. For randomization, the site https://www.sealedenvelope.com is used. All codes are recorded on paper and stored in specific envelopes. Each of the generated codes is kept separately inside the envelope and the secretary gives one of these envelopes to the patient before the patient enters the doctor's room. Accordingly, the next patient code is not predictable. The doctor determines which treatments to perform based on the patient's code. Only the physician performing the intervention will be aware of the code assigned to the patient. After evaluating the outcome, based on the patient's name, the collected information will be linked to the assigned code.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind study, patients are informed about their participation in the study. Both the researchers and participants were kept blinded to group allocation. To achieve this, identical unlabeled bottles were prepared and given to the patients using confidential coding
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Khorasgan branch
Street address
Vice Chancellor for Research Affairs, University Blvd., Arghwanieh, J Sharghi Street
City
Esfahan
Province
Isfehan
Postal code
8155139998
Approval date
2026-07-07, 1405/04/16
Ethics committee reference number
IR.IAU.KHUISF.REC.1405.160

Health conditions studied

1

Description of health condition studied
oral aphthae
ICD-10 code
K12.0
ICD-10 code description
Recurrent oral aphthae

2

Description of health condition studied
Lichen planus
ICD-10 code
L43
ICD-10 code description
Lichen planus

Primary outcomes

1

Description
Pain intensity
Timepoint
Beginning of study and end of study
Method of measurement
Based on visual pain scale

2

Description
Dry Mouth
Timepoint
Beginning of study and end of study
Method of measurement
Visit by a doctor

3

Description
Allergy and oral fungus
Timepoint
Beginning of study and end of study
Method of measurement
Visit by a doctor

Secondary outcomes

empty

Intervention groups

1

Description
In the first intervention group, a combination of 6 vials of betamethasone ampoules, nystatin drops (100,000 units), aluminum hydroxide syrup (40 mg), and diphenhydramine syrup (160 mg) was prepared. Patients then used the betamethasone mouthwash three times a day for 2 minutes each time, over a period of 14 days.
Category
Treatment - Other

2

Description
In the second intervention group, a combination of 6 vials of dexamethasone ampoules, nystatin drops (100,000 units), aluminum hydroxide syrup (40 mg), and diphenhydramine syrup (160 mg) was prepared. Patients then used the dexamethasone mouthwash three times a day for 2 minutes each time, over a period of 14 days.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental Clinic, Faculty of Dentistry
Full name of responsible person
Dr. Hamid Taherinia
Street address
Faculty of Dentistry, University Blvd., Arghwanieh, J Sharghi Street
City
Esfahan
Province
Isfehan
Postal code
8595158
Phone
+98 31 3535 4003
Email
taherinia@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University, Khorasgan branch
Full name of responsible person
Dr. Majid Meshkini
Street address
Vice Chancellor for Research Affairs, University Blvd., Arghwanieh, J Sharghi Street
City
Esfahan
Province
Isfehan
Postal code
8155139998
Phone
+98 31 3535 4001
Email
meshkini@miums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University, Khorasgan branch
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

Islamic Azad University, Khorasgan branch

Full name of responsible person
Dr. Hamid Taherinia

Position
Resident of Oral and Maxillofacial Diseases

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

Street address
Faculty of Dentistry, University Blvd., Arghwanieh, J Sharghi Street

City
Esfahan

Province
Isfehan

Postal code
8595158

Phone
+98 31 3535 4003

Email
taherinia@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University, Khorasgan branch

Full name of responsible person
Dr. Amir Mansour Shirani

Position
Faculty Member of the University

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Faculty of Dentistry, University Blvd., Arghwanieh, J Sharghi Street

City
Esfahan

Province
Isfehan

Postal code
8595158

Phone
+98 31 3535 4003

Email
shirani324@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University, Khorasgan branch

Full name of responsible person
Dr. Amir Mansour Shirani

Position
Faculty Member of the University

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Faculty of Dentistry, University Blvd., Arghwanieh, J Sharghi Street

City
Esfahan

Province
Isfehan

Postal code
8595158

Phone
+98 31 3535 4003

Email
shirani324@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No further information available.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

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

Clinical Study Report
No - There is not 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