Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of mouthwash containing betamethasone with mouthwash containing dexamethasone in reducing the pain level of patients with symptomatic oral lichen planus

Protocol summary

Study aim

Comparison of the effectiveness of betamethasone-containing and dexamethasone-containing mouthwash in reducing pain in symptomatic oral lichen planus

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 34 patients. The lottery method will be used for randomization.

Settings and conduct

This study will be performed in the Department of Oral and Maxillofacial Diseases of Tabriz Dental School. Patients will be randomly divided into two groups A and B. The total number of patients is 34, which will be placed in each group of 17. Double-blind correction will be performed in such a way that the patient and the researcher will not be aware of the contents of the bottles. The A-labeled bottle will contain 15 cc of betamethasone in combination with 200 cc of AlMg gastric syrup and the B bottle will contain 15 cc of dexamethasone in combination with 200 cc of AlMg gastric syrup. To measure the extent of changes in the severity of symptoms, the Visual Analog Scale (VAS) will be used and the amount of VAS on the first day of referral will be compared with 6 weeks later.

Participants/Inclusion and exclusion criteria

Admission requirements: Patients with symptomatic oral lichen planus; Conditions of absence: Patients with oral lichen planus for whom corticosteroids are contraindicated.

Intervention groups

In this study, patients in one group received a mouthwash containing betamethasone for the other group, given a mouthwash containing dexamethasone and the effectiveness of the two will be compared.

Main outcome variables

Change in pain values according to VAS criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220509054789N1**
Registration date: **2022-05-17, 1401/02/27**
Registration timing: **prospective**

Last update: **2022-05-17, 1401/02/27**
Update count: **0**

Registration date

2022-05-17, 1401/02/27

Registrant information

Name

Sahar Khademnezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3333 6097

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of mouthwash containing betamethasone with mouthwash containing dexamethasone in reducing the pain level of patients with symptomatic oral lichen planus

Public title
Comparison of the effectiveness of mouthwash containing betamethasone with dexamethasone in reducing the pain level of oral lichen planus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with symptomatic OLP who have not yet received treatment. Confirmation of OLP diagnosis by histological sampling Age over 18 years

Exclusion criteria:
Pregnancy Having uncontrolled diabetes Getting a stomach ulcer Having a systemic disease for which corticosteroids are contraindicated. Observation of dysplasia in the view of histopathology Get other treatments for OLP Infection of skin lesions Taking psychiatric drugs

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into two groups A and B. Sealed envelopes will be used for this purpose. They will be sealed by writing group A or B inside the envelopes. The envelopes are then mixed and the first envelope is removed at each patient's visit and assigned to the group inside the envelope. The examining dentist does not know which group A and B each belong to.

Blinding (investigator's opinion)
Double blinded

Blinding description
The double-blind method will be implemented, In this way, the patient, researcher and data analyzer will not be aware of the contents of the bottles. Sampling and assignment of individuals to each group will remain secret for the patient and the researcher until the end of the study. Bottles with similar appearance will be divided into two categories.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethics comittees of Tabriz university of medical sciences

Street address
Research Vice- Chancellor, Tabriz University of Medical Sciences, Golgasht Avenue, Tabriz, Iran, ,

City
Tabriz

Province
East Azarbaijan

Postal code
5166616471

Approval date
2022-04-20, 1401/01/31

Ethics committee reference number
IR.TBZMED.REC.1401.081

Health conditions studied

1

Description of health condition studied
Oral lichen planus

ICD-10 code
L43

ICD-10 code description
Lichen planus

Primary outcomes

1

Description
Pain

Timepoint
Before and 6 weeks after the intervention

Method of measurement
Use the Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 15 cc long-acting betamethasone (Kimia Drug Co.) in combination with 200 cc of AlMg stomach syrup, 3 times a day, 5 cc each time for 30

seconds, for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: 15 cc long-acting Dexamethasone (Kimia Drug Co.) in combination with 200 cc of AlMg stomach syrup, 3 times a day, 5 cc each time for 30 seconds, for 6 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty of Tabriz

Full name of responsible person

Sahar Khademnezhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Sahar Khademnezhad

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)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available