Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of mouthwashs containing betamethasone with dexamethasone in the improvement of oral lichen planus lesions: A randomized double blind placebo controlled trial

Protocol summary

Study aim
Comparing the effectiveness of mouthwashes containing betamethasone and dexamethasone in the improvement of oral lichen planus lesions

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 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. The Thongprasom scoring system will be used to measure the changes in the size of the lesions and the size of the lesions on the first day of visit 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
n 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
The extent of lesion size changes using the Thongprasom scoring system

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220509054789N2**
Registration date: **2022-07-23, 1401/05/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-23, 1401/05/01**
Update count: **0**

Registration date
2022-07-23, 1401/05/01

Registrant information

Name
Sahar Khademnezhad

Name of organization / entity

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Iran (Islamic Republic of)

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+98 41 3333 6097

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2023-01-21, 1401/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of mouthwashs containing betamethasone with dexamethasone in the improvement of oral lichen planus lesions: A randomized double blind placebo controlled trial

Public title
Comparing the effectiveness of mouthwashes containing betamethasone and dexamethasone in improving oral lichen planus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with OLP who have not received treatment so far. Confirmation of OLP diagnosis by histological sampling Age above 18 years

Exclusion criteria:
Pregnancy Having uncontrolled diabetes Stomach ulcer Having high blood pressure Suffering from a systemic disease for which corticosteroid administration is contraindicated Age below 18 years Observation of dysplasia in histopathological view Get other treatments for OLP

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: **60**

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
he 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
2022-06-27, 1401/04/06

Ethics committee reference number
IR.TBZMED.REC.1401.305

Health conditions studied

1

Description of health condition studied
Lichen planus

ICD-10 code
L43

ICD-10 code description
Lichen planus

Primary outcomes

1

Description
Lesions size

Timepoint
Before and 6 weeks after the intervention

Method of measurement
Using the Thongprasom scoring system

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. Patients will be instructed to gargle 5 cc each time for 30 seconds with betamethasone mouthwash inside their mouths, and to avoid eating and drinking for half an hour. In order to know about consumption or forgetting, the patients are asked to keep a diary and tick the consumption or non-consumption and hand it over to the researcher. This treatment will last up to 6 weeks. Then, after 6 weeks, the diameter of the lesions will be measured again.

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. Patients will be instructed to gargle 5 cc each time for 30 seconds with dexamethasone mouthwash inside their mouths, and to avoid eating and drinking for half an hour. In order to know about consumption or forgetting, the patients are asked to keep a diary and tick the consumption or non-consumption and hand it over to the researcher. This treatment will last up to 6 weeks . Then, after 6 weeks, the diameter of the lesions will be measured again.

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

Dentistry

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Position
Assistant professor

Latest degree
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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