Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Evaluating the effect of a combined mouthwash of triamcinolone acetonide 0.1% and Q10 coenzyme in the treatment of oral lichen planus

Protocol summary

Study aim
Determining the effect of a combined mouthwash of triamcinolone acetonide 0.1% and Q10 coenzyme in the treatment of oral lichen planus

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized

Settings and conduct
This study is performed on patients with oral lichen planus referred to the Oral Patients Department of Shahid Beheshti Dental School. In this study, the researcher and the patient will not know the type of drugs (double-blind), and patient examination and evaluation of oral lesions are done by one person before and after the treatment.

Participants/Inclusion and exclusion criteria
Patients with symptomatic oral lichen planus. Inclusion criteria: The diagnosis is clinical and in cases in which a definitive diagnosis of the lesion is difficult, a histopathological evaluation will be used. The patient should not have used topical corticosteroid treatments in the last two weeks or systemic corticosteroids in the last month. and also should not have used analgesics and anesthetics. Exclusion criteria: Patients with lichenoid lesions caused by medication or dental materials, Pregnant or lactating patients, Patients with other lesions such as leukoplakia and systemic lupus in conjunction with lichen planus, History of malignancy, Non-cooperative patients, and patients who do not use drugs

Intervention groups
One group of patients receive 0.1% triamcinolone mouthwash and the other group receives triamcinolone and coenzyme Q10 combined mouthwash. mouthwash will be used four times a day in the amount of 15 ml each time (by the measure) and then patients shouldn't eat or drink anything for half an hour. The mouthwash should be gargled in the mouth for two minutes. The patients will be Instructed how to use mouthwash.

Main outcome variables
Size of oral lesions Amount of healing Amount of pain and burning sensation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201127049502N1**
Registration date: **2020-12-01, 1399/09/11**
Registration timing: **prospective**

Last update: **2020-12-01, 1399/09/11**
Update count: **0**

Registration date
2020-12-01, 1399/09/11

Registrant information

Name
Arezoo Rahimzamani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2680 1139

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-20, 1399/09/30

Expected recruitment end date
2021-03-20, 1399/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of a combined mouthwash of triamcinolone acetonide 0.1% and Q10 coenzyme in the treatment of oral lichen planus

Public title
The effect of triamcinolone and Q10 coenzyme in the treatment of oral lichen planus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with symptomatic oral lichen planus (erosive or atrophic form) who have a sense of burning or pain. The diagnosis is clinical (Wickham striae or papules) and in cases in which a definitive diagnosis of the lesion is difficult, a histopathological evaluation will be used. The patient should not have used topical corticosteroid treatments in the last two weeks or systemic corticosteroids in the last month. The patient should not have used analgesics and anesthetics.

Exclusion criteria:
Patients with lichenoid lesions caused by medication or dental materials Pregnant or lactating patients Patients with other lesions such as leukoplakia and systemic lupus in conjunction with lichen planus History of malignancy Non-cooperative patients and patients who do not use drugs

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **18**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple method of randomization will be done. In this way, each patient is assigned a number (from 1 to 18), according to the referral time. Patients with odd numbers are then given mouthwash A and patients with even numbers are given mouthwash B. The type of each mouthwash A and B (which is triamcinolone mouthwash and which is triamcinolone and Q10 combination mouthwash) is unknown to the patient and researcher, and only the pharmacist is aware of that. At the end of the study, the type of mouthwashes will be asked for data decode and analysis.

Blinding (investigator's opinion)
Double blinded

Blinding description
Mouthwashes are provided in the same color, smell, and appearance, in bottles of the same shape. In this study, the researcher and the patient will not know the type of drugs. (double-blind) Patient examination and evaluation of oral lesions are done by one person before and after the treatment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Department of Oral Medicine, Shahid Beheshti University of Medical Sciences, Daneshjou Blvd, Chamran Hwy

City
Tehran

Province
Tehran

Postal code
1983963113

Approval date
2020-11-02, 1399/08/12

Ethics committee reference number
IR.SBMU.DRC.REC.1399.064

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
severity and size of the lesions based on REU index

Timepoint
baseline(day0), day15, day30

Method of measurement
Graded tongue blade

2

Description
amount of healing based on Efficacy Index
Timepoint
baseline(day0), day15, day30
Method of measurement
formula

3

Description
severity of burning sensation based on VAS Index
Timepoint
baseline(day0), day15, day30
Method of measurement
Scoring by the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, patients receive 0.1% triamcinolone mouthwash. mouthwash will be used four times a day in the amount of 15 ml each time (by the measure) and then patients shouldn't eat or drink anything for half an hour. The mouthwash should be gargled in the mouth for two minutes.
Category
Treatment - Drugs

2

Description
Intervention group: In this group, patients receive triamcinolone and coenzyme Q10 combined mouthwash. mouthwash will be used four times a day in the amount of 15 ml each time (by the measure) and then patients shouldn't eat or drink anything for half an hour. The mouthwash should be gargled in the mouth for two minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
school of dentistry, Shahid Beheshti university of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person
Arezoo Rahimzamani

Position
postgraduate student of oral medicine

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data

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Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
All data is potentially publishable after Anonymizing patients' identities

When the data will become available and for how long
Data will be available 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Researchers working in academic and scientific institutions

From where data/document is obtainable
Researchers working in academic and scientific institutions should send an email to the corresponding person and request the data

What processes are involved for a request to access data/document
Researchers working in academic and scientific

institutions should send an email to the corresponding person and request the data

Comments