

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)

Phone

+98 21 2680 1139

Email address

zamani_arezoo@yahoo.com

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

Arezoo Rahimzamani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Tehrani

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Email

Denttl@sbmu.ac.ir

Web page address

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

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahin Bakhshi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Name of organization / entity

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Arezoo Rahimzamani

Position

Postgraduate student

Latest degree

Medical doctor

Other areas of specialty/work

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