Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of adding photodynamic therapy to corticosteroid mouthwash on the Treatment of ulcerative-erosive oral lichen planus

Protocol summary

Study aim
To determine the effect of adding photodynamic therapy to corticosteroid mouthwash on the Treatment of ulcerative-erosive oral lichen planus

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 36 patients. Random-Allocation software version 1.0.0 was used for randomization.

Settings and conduct
Patients with ulcerative-erosive lichen planus who are referred to the Oral Diseases Department of Isfahan Dental School during 2025-2026 will be included in the study if they are eligible and will be randomly assigned to intervention and control groups using a randomized block design. This study will be conducted in a double-blind manner, with patients and those performing patient assessments unaware of the allocation of individuals to groups.

Participants/Inclusion and exclusion criteria
Inclusion Criteria; Patients with ulcerative-erosive oral lichen planus, whose disease was confirmed by histopathological examination. Exclusion criteria; Lesions that have evidence of dysplasia in the histopathological view, contact or medicinal lichenoid lesions, patients who have received oral treatment for their lichen planus during the last month, pregnant and lactating patients, people with uncontrolled systemic disease and photosensitive people.

Intervention groups
Intervention groups: mouthwash 0.5mg dexamethasone was used and in photodynamic therapy, the photosensitizer toluene chloride and Lisotronics (semiconductor diode laser - Warsaw Poland) with a wavelength of 635nm for four sessions was used. Control group: mouthwash 0.5mg of dexamethasone was used and in photodynamic therapy, the photosensitizer toluene chloride and placebo Lisotronics (semiconductor diode laser - Warsaw Poland). This means that because they are wearing protective glasses, they do not notice that the laser is off) for four sessions was used.

Main outcome variables
pain score, lesion size score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150609022628N1**
Registration date: **2025-07-19, 1404/04/28**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-19, 1404/04/28**
Update count: **0**

Registration date
2025-07-19, 1404/04/28

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 5512

Email address
khozeimeh@dnt.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-13, 1404/02/23

Expected recruitment end date
2025-08-21, 1404/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of adding photodynamic therapy to corticosteroid mouthwash on the Treatment of ulcerative-erosive oral lichen planus

Public title
The effect of photodynamic therapy on the Treatment of ulcerative-erosive oral lichen planus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with ulcerative-erosive oral lichen planus, whose disease was confirmed by histopathological examination.

Exclusion criteria:
Lesions that have evidence of dysplasia in the histopathological view contact or medicinal lichenoid lesions patients who have received oral treatment for their lichen planus during the last month pregnant and lactating patients people with uncontrolled systemic disease photosensitive people

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
This study will be conducted on 36 patients with oral ulcerative-erosive lichen planus. Using the Random-Allocation version 1.0.0 software, patients will be randomly assigned to two groups in a block-wise manner. First, the number of possible formations of blocks of four (including two people from the intervention group and two people from the control group) is determined, and from the six possible formations of these groups, 9 selections are made to ultimately have 9 blocks of four.The sequence of placement of individuals is determined based on these blocks and the names of the two groups are written on 36 cards based on the same random sequence and each is placed in a sealed envelope to ensure allocation concealment. After that, when the eligible individuals start to apply, the envelopes are opened in the order of their application and the group in which the individual is to be placed is determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a randomized double blind clinical trial. In this study, both groups of patients receive the main treatment, but in the intervention group, laser is used, while in the control group, we use a sham laser.The people who evaluate the patient are unaware of the assignment of people to groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Faculties of Dentistry, Health and Modern Medical Technologies, Isfahan University of Medical Scienc

Street address
Hezarjrib Street, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran

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8174673461

Approval date
2025-05-07, 1404/02/17

Ethics committee reference number
IR.MUI.DHMT.REC.1404.028

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
Pain Score

Timepoint
Before starting intervention , one week, two weeks, one month and two months after starting intervention

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Lesion size score
Timepoint
Before starting intervention, one week, two weeks, one month and two months after starting intervention
Method of measurement
Graded abslang

Intervention groups

1

Description
Control Group : The Control group Patients receive mouthwash containing corticosteroid (0.5 mg of dexamethasone in 5 ml of water) as a standard first-line treatment; Then 30 minutes later, 100,000 units of nystatin solution is applied to prevent candidiasis. Treatment with mouthwash is done 4 times a day. In addition, patients are treated with sham photodynamic therapy. To carry out photodynamic therapy, the photosensitizer tolonium chloride is used on the lesion and 0.5 mm around the lesion using a sterile swab; Then, after 15 minutes, the lesion and 0.5 mm around the lesion a re exposed to sham laser (placebo) In a way that the patient is unaware laser unit is off due to wearing protective eyewear. In order to cover the entire parts of the lesion, in larger lesions, irradiation is performed in several points. In this study, lasotronix semiconductor diode laser (Warsaw, Poland) with a wavelength of 635 nm and a series diameter of 8 mm is used, and the duration of radiation at each point is 15 seconds (according to the manufacturer's instructions). According to the protocol presented in Sadaksharam's study, photodynamic therapy treatment is performed in 4 sessions on days 1, 4, 7 and 15. According to Sadaksharam's study, the follow-up sessions in this study are one week, two weeks, one month and two months after the start of intervention.
Category
Treatment - Devices

2

Description
Intervention group: Patients in intervention groups receive mouthwash containing corticosteroid (0.5 mg of dexamethasone in 5 ml of water) as a standard first-line treatment; Then, 30 minutes later, 100,000 units of nystatin solution is applied to prevent candidiasis. Treatment with mouthwash is done 4 times a day. In addition, patients in the intervention group are treated with photodynamic therapy.To carry out photodynamic therapy, the photosensitizer tolonium chloride is used on the lesion and 0.5 mm around the lesion using a sterile swab; Then, after 15 minutes, the lesion and 0.5 mm around the lesion a re exposed to laser radiation. In order to cover the entire parts of the lesion, in larger lesions, irradiation is performed in several points. In this study, lasotronix semiconductor diode laser (Warsaw, Poland) with a wavelength of 635 nm and a series diameter of 8 mm is used, and the duration of radiation at each point is 15 seconds and the radiation power is 400 mW (according to the manufacturer's instructions). Laser radiation is done in contact mode.According to the protocol presented in Sadaksharam's study, photodynamic therapy treatment is performed in 4 sessions on days 1, 4, 7 and 15. According to Sadaksharam's study, the follow-up sessions in this study are one week, two weeks, one month and two months after the start of intervention.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Dentistry Of Isfahan University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Faezeh Khozeimeh
Position
Associate Professor
Latest degree
Specialist
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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identification.
When the data will become available and for how long
Access period starts 2 months after results are published
To whom data/document is available
The data is made available to anyone who needs this

information.

Under which criteria data/document could be used

Anyone who needs this data can email the main project manager and, if they agree, the data will be made available to them.

From where data/document is obtainable

Faezeh Khozeimeh- khozeimeh@dnt.mui.ac.ir

What processes are involved for a request to access data/document

After sending an email to the main project manager and reviewing them, they can receive the information they need within a month.

Comments