

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison the effect of topical corticosteroid with photodynamic therapy and topical corticosteroid on pain and size of lesions in oral lichen planus patients

Protocol summary

Summary

In this study, the efficacy of toluidine blue-mediated photodynamic therapy and topical corticosteroid on decreasing pain and size of oral lichen planus (OLP) lesions will be compared. This randomized double blind clinical trial will compare the therapeutic effect of photodynamic therapy and corticosteroid on OLPs (atrophic/ erosive/ ulcerative forms). Eleven patients with bilateral oral OLP lesions (22 affected sides) will be recruited in this study during 2016-2017 in Oral and Maxillofacial Department affiliated by Shiraz School of Dentistry. The patients with clinical or histopathology diagnosis of bilateral atrophic or erosive OLP with no other inflammatory diseases or malignancies who sign the written consent form will be recruited. These 22 sides will be randomly divided to control and intervention sides. Every 2 sides of each patient's mouth (oral mucosa) will be randomly allocated to the intervention or control group. Random allocation will be done through block randomization method. Toluidine blue will be applied on the lesion of intervention side. Then after 10 min, the lesions will be irradiated with a 660nm diode laser for 10 min(power: 25mW). But in control side of oral mucous (other side of the mouth), only sham laser will be used. The therapeutic effects of PDT will be obtained by the activation of toluidine blue. These interventions will be applied on days 3, 5 and 7. In week 3, topical corticosteroid (triamcinolone acetonide 0.1% three times a day) will be prescribed for all the patients who will participate in this research. They will be followed up on weeks 3, 5 and 7. In each session the size of oral lesions and level of pain will be assessed by Thongprasom sign scoring and VAS. Finally the scores will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606208585N2**

Registration date: **2017-08-02, 1396/05/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-02, 1396/05/11

Registrant information

Name

Fatemeh Lavaee

Name of organization / entity

Shiraz Dental School

Country

Iran (Islamic Republic of)

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+98 71 1631 9309

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shiraz University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-08-30, 1396/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision the effect of topical corticosteroid with photodynamic therapy and topical corticosteroid on pain and size of lesions in oral lichen planus patients

Public title

The effect of photodynamic therapy on oral lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Histopathologically and clinically confirmed oral lichen planus Bilateral atrophic or erosive or ulcerative oral lichen planus Signing informed consent
Exclusion criteria: The patients under 18 years old
Positive history of other inflammatory diseases, malignancies or even dysplastic lesions The patients who have received treatment for oral lichen planus lesions since a previous month Pregnant women The patients with history of photo sensitivity

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The oral lichen planus lesions of patients will be divided to intervention side and control side by block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Science

Street address

Shiraz University of Medical Science, Namazi square, Zand street, Shiraz, Iran

City

Shiraz

Postal code

Approval date

2016-10-09, 1395/07/18

Ethics committee reference number

IR.SUMS.REC.1395.124

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

day1, 3, 5, week 3, 5, 7

Method of measurement

VAS

2

Description

size

Timepoint

day1, 3, 5, week 3, 5, 7

Method of measurement

scaled tongue blade(mm)

3

Description

clinical presentation or inflammation

Timepoint

day1, 3, 5, week 3, 5, 7

Method of measurement

Thongprasom sign scoring

Secondary outcomes

1

Description

toluidine blue hypersensitivity

Timepoint

day1, 3, 5

Method of measurement

clinical symptom of hypersensitivity

Intervention groups

1

Description

In intervention side (one side of the patients' mouth), photodynamic therapy will be applied for erosive/ulcerative lesions on day 1, 3, 5. Topical toluidine blue will be applied with micropipette for intervention side and after 10 min, the lesion will be irradiated with a 660nm diode laser for 10 min(power: 25mW). No corticosteroid therapy will be prescribed during 2 weeks from last PDT session. After two weeks, topical triamcinolone [triamcinolone acetonide 0.1% (Teriident) manufactured by Raha pharma.co, Isfahan, Iran] should be used topically after each meal three times a day. Patients will be followed up in week 5 and 7.

Category

Treatment - Other

2

Description

In control side (other side of the mouth), topical toluidine blue with micropipette and sham laser irradiation will be on day 1, 3 and 5. After two weeks, topical triamcinolone [triamcinolone acetonide 0.1%(Teriident) manufactured by Raha pharma.co, Isfahan, Iran] should be used topically after each meal, three times a day. The patients will be followed up on week 5 and 7.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Shiraz University of Medical Sciences

Full name of responsible person

Dr.Fateme Lavaee

Street address

Shiraz Dental School, Ghasrdasht street, Shiraz, Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shiraz University of Medical Science

Full name of responsible person

Dr. Basir Hashemi

Street address

Shiraz university of Medical Science, Zand street, Iran

City

Shiraz

Grant name

Grant code / Reference number

95-01-03-11515

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Shiraz University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Oral and Maxillofacial Medicine Department, School of Dentistry, Shiraz University of Medical Science

Full name of responsible person

Fatemeh Lavaee

Position

Assistant Professor of Oral and Maxillofacial Medicine Department

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty