

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison the effect of dexamethasone mucoadhesive and triadent on the size and pain of oral lichen planus lesions

#### Protocol summary

##### Study aim

The aim of this study is preparing mucoadhesive form of dexamethasone and evaluation of its efficacy

##### Design

Clinical trial phase 2-3 with control group, with parallel groups, randomised trial with blinded outcome assessment

##### Settings and conduct

This study will be done on patients with oral lichen planus lesions who will be referred to Oral and Maxillofacial Disease Department of Shiraz Dental School. In one group, the dexamethasone mucoadhesive and triadent will be prescribed for the other group. The assessor of outcomes will be blinded to the type of prescribed medication.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients with atrophic or erosive oral lichen planus The patients with histopathology and clinically conformed lichen planus The patients who will be referred to Oral and Maxillofacial Disease Department of Shiraz Dental School Exclusion criteria: The patients with history of other inflammatory diseases The patients with history of malignancies or even dysplastic lesions The patients who have received treatment for oral lichen planus lesions since a previous month pregnant women

##### Intervention groups

Intervention group: The patient in intervention group will receive new designed dexamethasone mucoadhesive. This mucoadhesive will be used topically two times a day for 2 weeks and the next 2 weeks they will use the mucoadhesive once a day. The ointment will be retained for 5 minutes and then spitting. Control group: In this group patients will receive triadent 0.1% Razi company , 2 times a day for 2 weeks and the next 2 weeks they will use the mucoadhesive once a day. The ointment will be retained for 5 minutes and then spitting.

##### Main outcome variables

Pain, size

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120101008585N7**

Registration date: **2019-01-11, 1397/10/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-11, 1397/10/21**

Update count: **0**

##### Registration date

2019-01-11, 1397/10/21

##### Registrant information

##### Name

Fatemeh Lavaee

##### Name of organization / entity

Shiraz Dental School

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1631 9309

##### Email address

lavaeef@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-31, 1397/10/10

##### Expected recruitment end date

2019-08-23, 1398/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparision the effect of dexamethasone mucoadhesive and triadent on the size and pain of oral lichen planus lesions

## Public title

Evaluation the effect of dexamethasone mucoadhesive on oral lichen planus lesions

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

The patients with atrophic or erosive oral lichen planus  
The patients with histopathology and clinically conformed lichen planus  
The patients who will be referred to Oral and Maxillofacial Disease Department of Shiraz Dental School

### Exclusion criteria:

The patients with history of other inflammatory diseases  
The patients with history of malignancies or even dysplastic lesions  
The patients who have received treatment for oral lichen planus lesions since a previous month  
pregnant women

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Each block with 4 allocations, consisting 2 allocation for intervention and 2 for control group will be considered. Six possible sequence of treatment allocation in each block will be listed and each one will be written on a card. Each time a block will be selected and the sequence of treatment will be registered until the treatment allocations become completed for all 30 participants (8 blocks). The randomization was performed by a methodologist. Allocation concealment will be done by the main researcher. On each 30 cards a sequence will be written and sealed. Pockets will be put in a box. A pocket will be allocated for each participant based on order of enrollment.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The outcome assessor will be blinded to the type of prescribed medication.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

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

##### City

Shiraz

##### Province

Fars

##### Postal code

7186781559

#### Approval date

2018-12-25, 1397/10/04

#### Ethics committee reference number

IR.SUMS.REC.1397.925

## 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

#### Timepoint

Week 1,2,4

#### Method of measurement

Visual analogue scale

### 2

#### Description

Size

#### Timepoint

Week 1,2,4

#### Method of measurement

Scaled tongue blade(mm)

### 3

#### Description

Clinical presentation or inflammation

#### Timepoint

Week 1,2,4

### Method of measurement

Thongprasom sign scoring

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The patient in intervention group will receive new designed dexamethasone mucoadhesive. This mucoadhesive will be used topically two times a day for 2 weeks and the next 2 weeks they will use the mucoadhesive once a day. The ointment will be retained for 5 minutes and then spitting. After breakfast and dinner mucoadhesive will be prescribed and the participants should refuse eating and drinking up to 30 minutes after application of Dexamethasone.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: In this group patients will receive triadent 0.1% Razi company , 2 times a day for 2 weeks and the next 2 weeks they will use the mucoadhesive once a day. The ointment will be retained for 5 minutes and then spitting. After breakfast and dinner mucoadhesive will be prescribed and the participants should refuse eating and drinking up to 30 minutes after application of Triadent.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

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

##### City

Shiraz

##### Province

Fars

##### Postal code

7186781559

##### Phone

+98 71 3626 3193

##### Email

lavaeef@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr.Ghhasemi

##### Street address

Shiraz university of Medical Sciences, Zand street, Iran

##### City

Shiraz

##### Province

Fars

##### Postal code

7186782559

##### Phone

+98 71 3212 2438

##### Email

ghasemim@summs.ac.ir

#### Grant name

#### Grant code / Reference number

97-01-99-17149

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

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Fatemeh Lavaee

##### Position

Assistant Professor of Oral and Maxillofacial Medicine Department

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

##### Street address

Shiraz School of Dentistry, Ghasrdasht street, Shiraz, Iran

##### City

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##### Province

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**Email**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh Lavaee

**Position**

Assistant Professor of Oral and Maxillofacial Medicine  
Department

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh Lavaee

**Position**

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Department

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**Other areas of specialty/work**

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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 collected data will be shared after deidentification of  
participants.

**When the data will become available and for how long**

6 months after publication data will become available.

**To whom data/document is available**

The researchers in academic institutions

**Under which criteria data/document could be used**

The researchers in academic institutions.

**From where data/document is obtainable**

The researchers in academic institutions can email  
responsible person and request information

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

The researchers in academic institutions can email  
responsible person and request information.

**Comments**