Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparision 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

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7186781559

Phone

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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

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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

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Shiraz School of Dentistry, Ghasrdasht street, Shiraz, Iran

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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

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

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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