Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Laboratory Indexes and Therapeutic Effects of Two Mucoadhesive Systems Containing Clobetasol on Oral Lichen Planus

Protocol summary

Study aim

1. Comparison of mucosal adhesion of two forms of Clobetasol gel 2. Comparison of pain score, lesions size, and quality of life 3. Comparison of recovery time, according to Thongprasom index

Design

Patients will randomly divided into two groups with 22 individuals: The first group will be prescribed mucoadhesive Clobetasol with formulation 1 The second group will be prescribed mucoadhesive Clobetasol with formulation 2

Settings and conduct

44 patients with oral lichen planus, referred to Isfahan Dental School, will be selected and will be divided into two groups with 22 individuals. Patients will be treated with mucoadhesive Clobetasol for one month and oral lesions will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Diagnosis of oral lichen planus according to clinical criterias and histopathology 2. The age range: 16-70 years old 3. Non-use of local or systemic drugs to treatment of lichen planus (one week before start of the study) 4. Severity of lesions with 3, 4, and 5 scores according to Thongprasom index 5. Non-use of immunosuppressive drugs (one week before start of the study) 6. Non-use of drugs which cause lichenoid reaction (one week before start of the study) Exclusion criteria: 1. Pregnancy and breastfeeding 2. Use of drugs which cause lichenoid reaction 3. Use of immunosuppressive drugs 4. Existence of any systemic disease other than lichen planus (example: viral, bacterial, and fungal infections; acute peptic ulcer; acute glomerulonephritis; myasthenia gravis) 5. Existence of lesions in direct contact with amalgam-treated teeth 6. Allergy to corticosteroids

Intervention groups

Two forms of mucoadhesive Clobetasol will be used to treatment of patients with lichen planus lesions

Main outcome variables

Pain score Life quality index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200425047195N1**
Registration date: **2020-12-07, 1399/09/17**
Registration timing: **retrospective**

Last update: **2020-12-07, 1399/09/17**
Update count: **0**

Registration date

2020-12-07, 1399/09/17

Registrant information

Name

Faezeh Khozeimeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3267 5638

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-26, 1399/07/05

Expected recruitment end date

2020-12-05, 1399/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Laboratory Indexes and Therapeutic Effects of Two Mucoadhesive Systems Containing Clobetasol on Oral Lichen Planus

Public title
Effects of two mucoadhesive forms of Clobetasol on oral lichen planus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of oral lichen planus according to clinical criterias and histopathology The age range: 16-70 years old Non-use of local or systemic drugs to treatment of lichen planus (one week before start of the study) Severity of lesions with 3, 4, and 5 scores according to Thongprasom index Non-use of immunosuppressive drugs (one week before start of the study) Non-use of drugs which cause lichenoid reaction (one week before start of the study)

Exclusion criteria:
Pregnancy and breastfeeding Use of drugs which cause lichenoid reaction Use of immunosuppressive drugs Existence of any systemic disease other than lichen planus (example: viral, bacterial, and fungal infections; acute peptic ulcer; acute glomerulonephritis; myasthenia gravis) Existence of lesions in direct contact with amalgam-treated teeth Allergy to corticosteroids

Age
From **16 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of quadruple blocks: size of the blocks is randomly selected. In each block, there is an equal number from each group. In quadruple blocks, two case groups and two control groups are considered

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, two mucoadhesive forms of Clobetasol will be compared. The drug forms are simulated and therefore participants of the study will have no information about the two drug forms.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jerib St.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2020-09-26, 1399/07/05

Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.176

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 intensity

Timepoint
Evaluation of pain intensity at start of the study, and at the first, second, third and fourth weeks after use of mucoadhesive Clobetasol

Method of measurement
Visual scale of pain

2

Description
Size of erosive and atrophic areas of oral lichen planus

Timepoint
Evaluation of pain intensity at start of the study, and at the first, second, third and fourth weeks after use of mucoadhesive Clobetasol

Method of measurement
Thongprasom index

Secondary outcomes

1

Description
Life quality
Timepoint
Evaluation of life quality at start of the study, and at the first, second, third and fourth weeks after use of mucoadhesive Clobetasol
Method of measurement
Questionnaire of chronic oral mucosal diseases

Intervention groups

1

Description
Intervention group: 1. Consumables specifications: mucoadhesive gel clobetasol RDN 0.05%. Chemical composition and concentration: each 100 mg contains 50 mg Clobetasol Propionate. Drug consumption time: rubbed on the region four times a day. Duration of drug use: one month.
Category
Treatment - Drugs

2

Description
Intervention group: 2. Consumables specifications: mucoadhesive Clobetasol Gel 0.05% made by Pharmaceutics. Chemical composition and concentration: each 100 mg contains 50 mg Clobetasol Propionate. Drug consumption time: rubbed on the region four times a day. Duration of drug use: one month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan University of Medical Sciences
Full name of responsible person
Faezeh Khozeimeh
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Department of Oral and Maxillofacial Diseases, School of Dentistry, Isfahan University of Medical Sciences, Hezar Jerib St.
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Sponsors / Funding sources

1

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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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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available