

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effectiveness of micro-needle assisted transmucosal delivery of hyaluronic acid and triamcinolone for oral lichen planus treatment

Protocol summary

Study aim

To determine the therapeutic efficacy of micro needling for transmucosal delivery of triamcinolone acetonide and hyaluronic acid on symptomatic oral lichen planus

Design

A parallel group, double blinded randomised trial (phase 3) on 10 patients. Randomized computer number generator will be used.

Settings and conduct

The subjects will be selected from OLP patients visiting the Oral Medicine Department of Shiraz University of Medical Sciences. Corticosteroid therapy (0.1% Triamcinolone acetonide (TA) mouth rinse twice a day for two months) and prophylactic antifungal therapy (fluconazole 200 mg once weekly) will be prescribed for all subjects during the study. However, the lesions in each group will be subjected to micro needling (MN) unilaterally with a Dermapen once a week for two weeks. Thereafter, 0.1% TA suspension and/or both 0.1% TA and 0.2% HA will be applied. Subjects who will be received HA in MN session, will be instructed to apply it on both sides twice a day for two weeks. Then, the outcome will be evaluated by two blinded oral medicine specialists and a statistical consultant.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1.subjects aged 18 years or older with bilateral symptomatic OLP lesions 2.Subjects who are willing to participate Exclusion Criteria: 1.Lichenoid reactions 2.History of drug allergy 3. Use of medication for OLP treatment or anticoagulants 4. Having oral candidiasis 5. Self-reported pregnancy or lactation

Intervention groups

Group A: •Control Side: Topical application of 0.1% triamcinolone acetonide (TA) •micro needling (MN) Side: Using MN technique as an adjunct to topical application of 0.1% TA Group B: •hyaluronic acid (HA) Side: Topical application of 0.1% TA and 0.2% HA •Combination Side: Using MN technique as an adjunct to topical application of both 0.1% TA and 0.2% HA

Main outcome variables

Pain level; Severity of the lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231213060357N1**

Registration date: **2024-02-17, 1402/11/28**

Registration timing: **prospective**

Last update: **2024-02-17, 1402/11/28**

Update count: **0**

Registration date

2024-02-17, 1402/11/28

Registrant information

Name

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2025-03-20, 1403/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of micro-needle assisted transmucosal delivery of hyaluronic acid and triamcinolone for oral lichen planus treatment

Public title

Effectiveness of micro-needling for oral lichen planus treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Subjects aged 18 years or older
Subjects diagnosed with OLP based on the clinical or histopathological findings according to the newest diagnostic approach published by American Academy of Oral and Maxillofacial Pathology in 2016
Subjects with bilateral symptomatic OLP lesions
Subjects who are willing to complete this clinical trial

Exclusion criteria:

Subjects with lesions that may be associated with lichenoid reactions
Subjects having a history of drug allergy
Subjects with a history of use of topical corticosteroids (in the past 4 weeks) or systemic corticosteroids (in the past 3 months) for oral lichen planus, other immunosuppressive treatments, retinoids, and anticoagulants
Subjects having oral candidiasis
Subjects with self-reported pregnancy or lactation

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: 10

More than 1 sample in each individual

Number of samples in each individual: 2

A split-mouth randomized clinical trial will be performed in each patient with bilateral lichen planus lesions.

Therefore, two different treatment plans will be performed in each patient.

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation will be performed using a computer random number generator to create a random number table. In more detail, subjects will be randomly attributed to (group A) or 1 (group B). Thereafter, lesions on the right side will be randomly attributed to (G1 in group A or G2 in group B) or 1 (G3 in group A or G4 in group B).

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the intervention provider will aware of the

treatment type, but to establish a blind evaluation, the scores for the parameters such as pain level and severity of lesions will be determined by two oral medicine specialists who will not involve in any step during patients' allocation, treatment delivery and micro needling. Therefore, they will be blinded to the type of intervention and study period. On the other hand, an independent statistician will perform the statistical analysis. It is important to note that every groups and the study subjects will have a code number to ensure his/her blinding (statistician). Therefore, this study will be double blind.

Placebo

Not used

Assignment

Parallel

Other design features

10 patients with bilateral lichen planus lesions will participate in this study. These patients will be divided into two groups with 5 subjects and the effectiveness of four different treatment plans will be determined and compared with each other. In this way, first the patients are randomly attributed to one of the two groups A or B, and then two different treatment plans will be performed in each patient with bilateral lesions. Therefore, two different treatment subgroups are defined in each group. The sample size estimation will be calculated based on a pilot study of 5 subjects in each group (A or B) at the 5% level of significance with power of 90%.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of School of Dentistry-Shiraz University of Medical Sciences

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Fars

Postal code

71348-14336

Approval date

2023-12-20, 1402/09/29

Ethics committee reference number

IR.SUMS.DENTAL.REC.1402.084

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 Level

Timepoint

At the beginning of the study (before the start of the intervention) and 14, 28, and 56 days after start

Method of measurement

Visual Analogue Scale

2

Description

Severity of the lesions

Timepoint

At the beginning of the study (before the start of the intervention) and 14, 28, and 56 days after start

Method of measurement

reticulation/erythema/ ulceration (REU) scoring system

Secondary outcomes

empty

Intervention groups

1

Description

Control group G 1: Control side in group A will be received topical 0.1% triamcinolone acetonide suspension (Exir, Iran) twice a day as the first line treatment during the study (for two months). Prophylactic antifungal therapy (fluconazole 200 mg once weekly) will be also prescribed during the study.

Category

N/A

2

Description

Intervention group G 2: Micro-needling (MN) side in group A will be subjected to MN once a week for two weeks and then received topical application of 0.1% triamcinolone acetonide (TA) suspension (Exir, Iran). Topical application of 0.1% TA twice a day for two months and prophylactic antifungal therapy (fluconazole 200 mg once weekly) will be also prescribed during the study.

Category

Treatment - Drugs

3

Description

Intervention group G 3: Hyaluronic acid (HA) side in group B will be received topical 0.2% HA (Gengigel,

Ricerfarma, Italy) twice a day for two weeks. Topical application of 0.1% triamcinolone acetonide suspension (Exir, Iran) twice a day for two months and prophylactic antifungal therapy (fluconazole 200 mg once weekly) will be also prescribed during the study.

Category

Treatment - Drugs

4

Description

Intervention group G 4: Combination side in group B will be subjected to MN once a week for two weeks and then received topical 0.2% Hyaluronic acid (HA) (Gengigel, Ricerfarma, Italy) and 0.1% triamcinolone acetonide (TA) suspension (Exir, Iran). Topical application of topical 0.2% HA twice a day for two weeks, 0.1% TA suspension twice a day for two months, and prophylactic antifungal therapy (fluconazole 200 mg once weekly) will be also prescribed during the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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
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
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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
Data can be shared after de-identifying individuals.

When the data will become available and for how long

Data will be available up to 6 months after publication.

To whom data/document is available

The researchers in academic and scientific institutions

Under which criteria data/document could be used

The researchers in academic and scientific institutions

From where data/document is obtainable

The data supporting the findings of this study will be

available upon reasonable request from the corresponding author.

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

The researchers in academic and scientific institutions can email the corresponding author and request for information.

Comments