

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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

Asma Sookhakian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3227 1592

##### Email address

asma.sookhakian@gmail.com

##### 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 (G) in group A or G\* in group B) or 1 (G\* 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

**Street address**

Shiraz University of Medical Science, Zand street

**City**

Shiraz

**Province**

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

Oral and Maxillofacial Medicine Department, Shiraz School of Dentistry

##### Full name of responsible person

Asma Sookhakian

##### Street address

Shiraz School of Dentistry, Ghasrodasht street

##### City

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##### Province

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##### Phone

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

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##### Full name of responsible person

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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**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Asma Sookhakian

**Position**

Postgraduate Student of Oral and Maxillofacial  
Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

**Contact**

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

Asma Sookhakian

**Position**

Postgraduate Student of Oral and Maxillofacial  
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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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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**