Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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 ۲۰۱۶ 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 ۴ weeks) or systemic corticosteroids (in the past ۳ 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 ۰ (group A) or ۱ (group B). Thereafter, lesions on the right side will be randomly attributed ۰ (G۱ in group A or G۳ in group B) or 1 (G۲ 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
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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

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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

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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

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