

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of intralesional injection of Hyaluronic Acid and Triamcinolone in Oral Lichen Planus

Protocol summary

Summary

Aims: Comparison of the treatment efficacy between hyaluronic acid/triamcinolone and triamcinolone alone administered intralesionally in terms of cure and recurrence rate of oral lichen planus lesions. Participants: Study population is from those patients referred to Oral and Maxillofacial Medicine Department, Faculty of Dentistry, Tehran University of Medical Sciences. Sample size is 28 people based on statistical formulation. Type of intervention: 7mg sterilized hyaluronic acid powder is dissolved in one triamcinolone acetone vial (40 mg/ml). Both preparation of hyaluronic acid/triamcinolone and triamcinolone are injected by 1 cc syringes into the oral lichen planus lesions which were divided into case and control groups randomly. Lesions were anesthetized by lidocaine 2% and epinephrine solutions. Cure and recurrence are followed after 14 and 28 days, and also after two, three, four, five, and six months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612241559N11**

Registration date: **2017-01-16, 1395/10/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-16, 1395/10/27

Registrant information

Name

Farzaneh Aghahoseini

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Private funding sources

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intralesional injection of Hyaluronic Acid and Triamcinolone in Oral Lichen Planus

Public title

The effect of Hyaluronic Acid and Triamcinolone in Oral Lichen Planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Bilateral presence of white reticular-papular lesions; histopathological criteria such as hydropic (liquefactive) degeneration of basal layer; band-like infiltration of mononuclear inflammatory cells in the superficial connective tissue; erosive/ulcerative form of lesion and atrophic/erythematous form of lesion.

Exclusion criteria: Dysplasia; systemic diseases; history of chemotherapy; history of radiotherapy; pregnancy and nursing; history of allergy to hyaluronic acid

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Vice chancellor for research of Tehran University of Medical Sciences, Qhods street, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2016-10-13, 1395/07/22

Ethics committee reference number

IR.TUMS.VCR.REC.1395.722

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

cure

Timepoint

14 days and 28 days after intervention and then monthly up to 6 month

Method of measurement

clinical examination

2

Description

recurrence

Timepoint

14 days and 28 days after intervention and then monthly up to 6 month

Method of measurement

clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: 7mg hyaluronic acid powder dissolved in one triamcinolone vial, via intralesionally injection, one time at the beginning of the treatment

Category

Treatment - Drugs

2

Description

control: triamcinolone, via intralesionally injection, one time at the beginning of the treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty of Tehran University of Medical Sciences

Full name of responsible person

khatereh Akbari

Street address

Department of Oral and Maxillofacial Medicine, Ground floor, Dental faculty of Tehran University of medical sciences, North Karegar street, beside Nuclear Energy Organization

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Private funding source

Full name of responsible person

Farzaneh Aghahoseini

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Department of Oral and Maxillofacial Medicine,
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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

Private funding source

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Dental faculty of Tehran University of Medical
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Full name of responsible person

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Position

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Full name of responsible person

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Position

Oral & Maxillofacial Medicine Board

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty