

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 acetonide 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

+98 21 6611 2437

Email address

aghahose@sina.tums.ac.ir

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

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

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
Sciences

Full name of responsible person

Khatereh Akbari

Position

Resident of Oral and Maxillofacial Medicine

Other areas of specialty/work**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

Postal code

1439955991

Phone

+98 21 4423 3115

Fax**Email**

kh_akbari@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Dental faculty of Tehran University of Medical
Sciences

Full name of responsible person

Farzaneh Aghahoseini

Position

Professor of Department of Oral and Maxillofacial
Medicine, Faculty of Dentistry, Tehran University

Other areas of specialty/work**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

Postal code

1439955991

Phone

+98 21 4279 4151

Fax**Email**

aghahose@sina.tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Dental faculty of Tehran University of Medical
Sciences

Full name of responsible person

Mahdieh Sadat Moosavi

Position

Oral & Maxillofacial Medicine Board

Other areas of specialty/work**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

Postal code

1439955991

Phone

00

Fax**Email**

ms-moosavi@sina.tums.ac.ir

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