Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Commitee 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 Univercity 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