Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Therapeutic Effect of Mucoadhesive Nano-Triamcinolone Gel and Conventional Triamcinolone Gel on Oral Lichen Planus

Protocol summary

Study aim

Comparison of Therapeutic Effect of Mucoadhesive Nano-Triamcinolone Gel and Conventional Triamcinolone Gel on Oral Lichen Planus

Design

40 patients with Erosive OLP were divided into two parallel groups receiving conventional Triamcinolone (CT) and Nano-Triamcinolone (NT)

Settings and conduct

The population of the study was 40 eligible patients with OLP referred to the dental research center and dentistry faculty at Isfahan university of medical sciences to participate and were randomly assigned to two groups of 20 each by random number generator software

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Definite Diagnosis of Lichen Planus via Clinial criteria and Histopathology approvement Range of 17 to 70 years old The clinical scores of OLP were evaluated on a Thongprasom scale, which categorizes in to 6 grades of (zero = perfectly healthy, 1 = mild white lines without inflammatory regions, 2 = white lines with atrophic regions smaller than 1 cm2, 3 = white lines with atrophic regions larger than 1 cm2, 4 = white lines accompanied with erosive regions less than 1 cm2, 5 = white lines with erosive areas larger than 1 cm2 Completion of Written Consent Exclusion Criteria: Breastfeeding usage of Drugs that cause Lichenoid Reactions usage of Immuno supressor Drugs Sensitivity to Corton Denture Usage

Intervention groups

The severity of pain was evaluated through visual analogue scale (VAS), the size of lesions was measured with paper lace, and the appearance of lesions was measured by Thongprasom scale

Main outcome variables

NT has a better impact on OLP in comparison with CT, but this difference is not statistically significant.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181226042133N1**
Registration date: **2019-01-08, 1397/10/18**
Registration timing: **retrospective**

Last update: **2019-01-08, 1397/10/18**
Update count: **0**

Registration date

2019-01-08, 1397/10/18

Registrant information

Name

Rastin Sadeghian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3625 3444

Email address

dr.rastinsadeghian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-10-10, 1395/07/19

Expected recruitment end date

2017-11-17, 1396/08/26

Actual recruitment start date

2016-10-10, 1395/07/19

Actual recruitment end date

2017-11-17, 1396/08/26

Trial completion date

2017-12-01, 1396/09/10

Scientific title

Comparison of Therapeutic Effect of Mucoadhesive Nano-Triamcinolone Gel and Conventional Triamcinolone Gel on Oral Lichen Planus

Public title

Comparison of Therapeutic Effect of Mucoadhesive Nano-Triamcinolone Gel and Conventional Triamcinolone Gel on Oral Lichen Planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definite Diagnosis of Lichen Planus via Clinial criteria and Histopathology approvement Range of 17 to 70 years old The clinical scores of OLP were evaluated on a Thongprasom scale, which categorizes the phenotype of OPL lesions and includes 6 grades (zero = perfectly healthy, 1 = mild white lines without inflammatory regions, 2 = white lines with atrophic regions smaller than 1 cm2, 3 = white lines with atrophic regions larger than 1 cm2, 4 = white lines accompanied with erosive regions less than 1 cm2, 5 = white lines with erosive areas larger than 1 cm2 Completion of Written Consent

Exclusion criteria:

Breastfeeding usage of Drugs that cause Lichenoid Reactions usage of Immuno supressor Drugs Sensitivity to Corton Denture Usage

Age

From **17 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **39**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

This triple-blind randomized clinical trial study (patient, examining physician, and statistic analyzer)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Aja University of Medical Sciences

Street address

West Fatemi St.-Etemadzadeh Alley

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2017-09-11, 1396/06/20

Ethics committee reference number

IR.REC.AJAUMS.1396.66

Health conditions studied

1

Description of health condition studied

Oral Lichen Planus

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The severity of pain, the size of lesions , Thongprasom scale

Timepoint

days of 2-4-6-14

Method of measurement

The severity of pain was evaluated through 100 mm visual analogue scale, the size of lesions was measured with paper lace, and the appearance of lesions was examined adopting Thongprasom scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients Receiving Nano-Triamcinolone

Category

Treatment - Drugs

2

Description

Control group: Patients Receiving non Nano-Triamcinolone

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental Faculty of Esfahan University of Medical Sciences

Full name of responsible person
دکتر عباسعلی خادمی

Street address
Hezar jerib St.

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Esfahan

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Isfehan

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+98 31 3668 0048

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Admin@dnt.mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Artesh University of Medical Sciences

Full name of responsible person
Sajjad Mehri

Street address
West Fatemi St.-Etemadzadeh Alley

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dr.rastinsadeghian@gmail.com

Grant name
Fifty Million Rial

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Artesh 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
Artesh University of Medical Sciences

Full name of responsible person
Rastin Sadeghian

Position
Dentist

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for updating data

Contact

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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
information of this research are accessible through forms for each patients and Measured citeria are in different pages without the reveal of patients names

When the data will become available and for how long
availability 2 months after publish of results

To whom data/document is available
Iran's National Elites Foundation-Aja university of medical sciences-Esfahan university of medical sciences-Pharmacology Industry

Under which criteria data/document could be used
Regarding the production of a more potent drug in case of Oral Lichen Planus Treatment

From where data/document is obtainable
Iran's National Elites Foundation

What processes are involved for a request to access data/document
Contacting Iran's National Elites Foundation and Dr Rouhani as the head of dental faculty of Research Centre of Aja university of medical sciences

Comments
This Project is conducted for Iran's National Elites Foundation