Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison between of the effect triamcinolone oral paste and silver nanoparticles gel on the lichen planus lesions healing in human model

Protocol summary

Study aim

In the human model, we will investigate the effect of gel containing silver nanoparticles and triamistolone ointment on the healing of lichen planus lesions in the human model.

Design

Clinical trial with control group, with parallel groups, single-blind, phase 1-2 on 40 patients. Randomization will be done by simple randomization using a sealed envelope containing one bead (white bead of the intervention group, red bead of the control group).

Settings and conduct

Patients with oral lichen planus are divided into two groups (intervention and control) by random block allocation method in the diagnosis department of the dental school. Gel containing silver nanoparticles will be prescribed for the intervention group and topical corticosteroid ointment 0.1% (triamcinolone) will be prescribed for the control group. The rate of improvement of the patients and the intensity of pain will be monitored at intervals of 2, 4 and 8 weeks after the start of the treatment. The study will be single blind. The outcome assessor is blinded to the placement of patients in the intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria - patients with definite diagnosis of lichen planus using clinical method and pathological sampling of erosive/atrophic lichen planus type, absence of dysplasia and patient's satisfaction. Exclusion criteria are pregnant women, injuries in contact with amalgam, use of drugs that cause lycanoid reactions, any treatment that has been done for these injuries, use of immunosuppressive drugs, history of sensitivity to silver.

Intervention groups

A gel containing silver nanoparticles will be prescribed for one group, and topical corticosteroid ointment 0.1% (triamcinolone) will be prescribed for the other group.

Main outcome variables

The rate of improvement of patients and the intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230823059242N1**
Registration date: **2024-06-03, 1403/03/14**
Registration timing: **retrospective**

Last update: **2024-06-03, 1403/03/14**
Update count: **0**

Registration date

2024-06-03, 1403/03/14

Registrant information

Name

Fatemeh Beheshti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3626 3193

Email address

fatemebeheshticync@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison between of the effect triamcinolone oral paste and silver nanoparticles gel on the lichen planus lesions healing in human model

Public title
The effect of gel containing silver nanoparticles and triamcinolone ointment on the healing of lichen planus lesions

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of lichen planus using clinical method and pathological tissue sampling Type of erosive/atrophic lichen planus Absence of dysplasia

Exclusion criteria:
Pregnant women Injuries in contact with amalgam The use of drugs that cause lycanoid reactions Any treatment that has been done for these injuries Use of immunosuppressive drugs A history of sensitivity to silver and the presence of any systemic disease

Age
No age limit

Gender
Both

Phase
1-2

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by random block method and using blocks of 4. In this way, first, 60 different quadruple blocks are created (ABBA, BABA, ABAB, BBAA, AABB and BABA), and one of these blocks is randomly selected. According to the order mentioned in the selected block, the patients will be divided into one of two groups A or B. Then randomization is done for other patients as well.

Blinding (investigator's opinion)
Single blinded

Blinding description
The outcome assessor is not aware of the placement of the patient in the intervention and control groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Zand St., Central Building of Shiraz University of Medical Sciences

City
Shiraz

Province
Fars

Postal code
7134814336

Approval date
2023-12-20, 1402/09/29

Ethics committee reference number
IR.SUMS.DENTAL.REC.1402.096

Health conditions studied

1

Description of health condition studied
lichen planus

ICD-10 code
L43

ICD-10 code description
lichen planus

Primary outcomes

1

Description
Recovery rate

Timepoint
At intervals of 2, 4 and 8 weeks after the intervention

Method of measurement
It will be evaluated based on the classification and criteria of Tangprasum. The classification of the clinical criteria of Tangprasum is as follows: 0) harmless 1) mild white lines without inflammatory areas 2) white lines with atrophic areas smaller than one square centimeter 3) white lines with atrophic areas larger than one square centimeter 4 (white lines with erosive areas smaller than one square centimeter 5) white lines with erosive areas larger than one square centimeter or with ulcerative lesions

2

Description
Pain

Timepoint
At intervals of 2, 4 and 8 weeks after the intervention

Method of measurement
Postoperative pain will be evaluated using a visual analog scale (VAS), with 10 ratings, from 0 for "no pain"

to 10 for "worst possible pain".

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: gel containing silver nanoparticles (Made By US-NANO), some gel is placed on the affected area three times a day after meals for 5 minutes. The treatment is done for two months
Category
Treatment - Drugs

2

Description
Control group: 0.1% topical corticosteroid ointment (triamcinolone, Iran Najo Pharmaceuticals), three times a day after meals, some gel is placed on the affected area for 5 minutes. The treatment lasts for two months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Diagnosis and Oral Diseases, School of Dentistry, Shiraz University of Medical Science
Full name of responsible person
Fatima Beheshti
Street address
Qomabad St. Qasrdasht - School of Dentistry
City
shiraz
Province
Fars
Postal code
1587871956
Phone
+98 71 3628 0112
Email
fatemebeheshticync@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mohammad hashem Hashempour
Street address
Zand St
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3235 7282
Email
hashempurm@sums.ac.ir
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
Fateme Beheshti
Position
Dental Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Qomabad St
City
Shiraz
Province
Fars
Postal code
7195615878
Phone
+98 71 3626 3193
Email
fatemebeheshticync@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person

Fateme Beheshti

Position
Dental Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

Street address
Qomabad St

City
Shiraz

Province
Fars

Postal code
7195615878

Phone
+98 71 3626 3193

Email
fatemebeheshticync@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Fateme Beheshti

Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It is not possible to access patient data

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available