Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of topical insulin in comparison of placebo in the treatment of patients with oral lichen planus

Protocol summary

Study aim
The aim of this study is to evaluate the effect and safety of topical insulin in the treatment of oral lichen planus.
Design
A double-blind clinical trial will be conducted as a control group (local normal saline) and an intervention group (local insulin) with 19 patients in each group. The randomization method will be based on block randomization.
Settings and conduct
The location of this study is the dermatology department of Razi Dermatology Hospital in Tehran. This study will be conducted on 38 oral lichen planus patients in a double-blind, block-blinded design from 2025 to 2026.
Participants/Inclusion and exclusion criteria
Inclusion criteria :˝All Patients with a confirmed diagnosis of Oral Lichen Planus . Exclusion criteria : Diabetic patients; Immunosuppressive patients; Pregnancy; Patients without systemic treatment
Intervention groups
Intervention group: 19 patients with oral lichen planus will be treated with topical insulin 1 unite per cc twice daily for three months. Control group: 19 patients with oral lichen planus will receive topical normal saline twice daily as a placebo.
Main outcome variables
Change in size of the lesion

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241208063991N1**
Registration date: **2025-05-16, 1404/02/26**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-16, 1404/02/26**
Update count: **0**
Registration date
2025-05-16, 1404/02/26

Registrant information
Name
Asheed Mohammed
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-04-19, 1404/01/30
Expected recruitment end date
2026-04-19, 1405/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of topical insulin in comparison of placebo in the treatment of patients with oral lichen planus

Public title
The effect of topical insulin on oral lichen planus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a confirmed diagnosis of Oral Lichen Planus

From any age group

Exclusion criteria:

Diabetic patients Immunosuppressive patients Pregnant ladies

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Random assignment of patients to local normal saline group (A) and local insulin group (B) will be done through block randomization as follows. In this way, each individual will be considered as a block. Binary blocks will be constructed in such a way that the AB combination (A means local normal saline, B means local insulin) will be given to the right of the individual and the local insulin to the left. Similarly, the BA combination will be given to the right of the individual and the local normal saline to the left. To prepare the random list, a random number table will be used in such a way that a random number will be selected at each stage. If the selected number will be between 0 and 4, the AB combination will be considered, and if the selected number will be between 5 and 9, the BA combination will be considered. In addition, in this study, blocks of 4, 6, and 8 will be used randomly to prepare the random list.

Blinding (investigator's opinion)

Single blinded

Blinding description

Both groups are given solutions without explanation of the type of solution, and the code is written as the letter A on the insulin solution and the letter B on the normal saline solution, which can be distinguished by the research team. Assignment to group A or B will be done based on a random table.

Placebo

Not used

Assignment

Parallel

Other design features

No

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committe of College of Medicine, Tehran University of Medical Science

Street address

Razi Hospital, Vahdat-e- eslami streat, Shapour square, Tehran

City

Tehran

Province

Tehran

Postal code

1416753955

Approval date

2024-11-13, 1403/08/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1403.379

Health conditions studied

1

Description of health condition studied

Oral Lichen planus

ICD-10 code

L43.9

ICD-10 code description

Lichen planus, unspecified

Primary outcomes

1

Description

The size of oral lichen planus lesions

Timepoint

Measurement of oral lichen planus lesion size will be performed at the beginning of the study (before the intervention begins) and 1, 2, and 3 months later

Method of measurement

The size of the waste will be measured with a ruler (unit: centimeters).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 19 patients receive topical insulin, 1 cc of regular topical insulin, 2 units per cc, twice daily for 3 months. Patients will be visited monthly and lesion size will be measured in square centimeters and photographs will be taken. Control group: 19 patients receive topical normal saline. In the second group, topical normal saline will be applied twice daily for 3 months. Patients will be visited monthly and lesion size will be measured in square centimeters and photographs will be taken.

Category

Treatment - Drugs

2

Description
Control group: 19 patients will receive topical normal saline. In this group, topical normal saline will be applied to the lesions twice a day, one cc, for three months. Patients will be visited every month and the size of the lesion will be measured in square centimeters and a photograph will be taken of the patient.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Dermatology Hospital

Full name of responsible person
Ashid Mohamed

Street address
Razi alley, Vahdat-e-eslami streat

City
Tehran

Province
Tehran

Postal code
1416753955

Phone
+98 910 752 7437

Email
asheed.almohammadi94@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Ramin Kordi

Street address
Razi alley, Vahdat-e-eslami streat

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Email
nsm.maryam@gmail.com

Grant name
Tehran University of Medical Science

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Ashid Mohamed

Position
Resident in dermatology

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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No 64, Khandan alley ,Vahdat-e-eslami street

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Asheed Mohamed

Position
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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Asheed Mohamed

Position

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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

Data for all variables is provided upon request

When the data will become available and for how long

Data will be available all the time on request

To whom data/document is available

Data will be available for academic institution

Under which criteria data/document could be used

Data will be provided for other academic institution. Requests should be approved by Tehran University of Medical science

From where data/document is obtainable

Tehran University of Medical Science

What processes are involved for a request to access data/document

The process of obtaining data involve the research center in tehran university of medical science/ dermatology department.

Comments

no additional comments