Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the therapeutic effects of Nanomicelle Curcumin in oral lichen planus patients

Protocol summary

Study aim

Primary Objective: Compare systemic nanomicelle curcumin with topical dexamethasone plus nystatin in oral lichen planus. Practical Objective: Assess nanomicelle curcumin as a plant-based alternative if equally effective. Specific Objectives: Evaluate and compare antifungal, analgesic, and lesion severity effects of nanomicelle curcumin versus topical dexamethasone plus nystatin in patients with oral lichen planus.

Design

Phase 3, triple-blind, randomized clinical trial on 60 oral lichen planus patients, divided into two groups: nanomicelle curcumin capsules (intervention) and dexamethasone mouthwash plus nystatin (control). Randomization by block method using sealed envelopes.

Settings and conduct

Mashhad University of Medical Sciences – School of Dentistry – Oral and Maxillofacial Diseases Research Center - Evaluations will be conducted at weeks 1, 2, and 4 And includes examinations and sterile swab sampling from the surface of the tongue.

Participants/Inclusion and exclusion criteria

Inclusion: Erosive/atrophic OLP (Modified WHO), Thongprasom ≥2, ASA I/II, CFU >500/g tongue, age ≥18, consent, no allergies, no dentures/ortho, non-smoker, not pregnant/breastfeeding, no recent relevant meds or candidiasis risk. Exclusion: Lichenoid reaction, severe adverse effects, drug allergy, pregnancy, non-compliance or withdrawal.

Intervention groups

Intervention:Receives nanocurcumin only (Sinacurcumin capsules, 80 mg)./Control:Receives topical corticosteroid (0.5 mg dexamethasone mouthwash, Abureyhan Pharmaceutical) plus nystatin suspension (100,000 units/mL, Jaber Ibn Hayyan Pharmaceutical).

Main outcome variables

Thongprasom criteria - Visual Analog Scale (VAS) - Colony Forming Units (CFU) count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250714066493N1**
Registration date: **2025-07-19, 1404/04/28**
Registration timing: **prospective**

Last update: **2025-07-19, 1404/04/28**
Update count: **0**

Registration date

2025-07-19, 1404/04/28

Registrant information

Name

Helia Khosromanesh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-06, 1404/06/15

Expected recruitment end date

2026-01-05, 1404/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effects of Nanomicelle Curcumin in oral lichen planus patients

Public title

effects of Nanomicelle Curcumin in oral lichen planus patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive Diagnosis of Erosive/Atrophic Lichen Planus: Based on the Modified WHO Classification Criteria Lesion severity in the patient must be scored as 2 or higher based on the Thongprasom criteria. The patient must fall under ASA physical status classification I or II in terms of systemic health. The CFU count obtained from the dorsal surface of the tongue must exceed 500 CFU/g. Informed consent to participate in the study. No history of drug hypersensitivity: patients must not have any history of allergic reactions to the medications used in the study. Ability and willingness to cooperate: including the ability to take medications regularly and attend follow-up visits. Absence of local or systemic predisposing factors for candidiasis, such as the use of inhaled or topical corticosteroids, presence of hyperkeratosis, use of immunosuppressive drugs, etc. No history of systemic antibiotic use within two weeks prior to the start of the study. No use of systemic or topical antifungal agents for any reason. No history of topical corticosteroid use within two weeks prior to the start of the study. Women must not be pregnant or breastfeeding during the study period. No use of dentures or orthodontic appliances. No tobacco use. No history of turmeric allergy.

Exclusion criteria:

Likelihood of Lichenoid Reaction Based on Clinical Presentation, Histopathology, and the Modified WHO Classification Criteria Occurrence of severe adverse effects: In the event of any severe side effects, the patient will be withdrawn from the study Pregnancy during the course of the study Development of allergic reactions to the prescribed medications during the study period Failure to complete the treatment course for any reason, including participant withdrawal from the study or non-adherence to the treatment protocol Failure to meet the previously stated inclusion criteria

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 60 patients will be randomly assigned into two groups of 30 using block randomization. This method will be employed to ensure a balanced distribution of participants between the intervention and control groups and to reduce heterogeneity in treatment-related factors such as age, gender, and disease severity. Random allocation will be performed using blocks of four with a 1:1 ratio. The Random Allocation Software (RAS) will be used for this purpose.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding Procedure and Sample Allocation: To ensure blinding at the patient level, due to the differences in the method of administration between the intervention group (systemic therapy) and the control group (topical therapy), only the general objectives of the study and the fact of being assigned to one of the treatment groups will be disclosed to the participants—without revealing the specific treatment methods used in each group. To maintain blinding at both the patient and researcher levels, drug delivery and the necessary instructions will be provided individually and separately for each participant by a person outside of the research team. To further maintain patient-level blinding throughout the study, outcome assessments for the intervention and control groups will be conducted on separate days (even and odd days), by an evaluator who is blinded to the patients' group allocations. Patient data will be entered into an Excel file using unique ID codes, and the identity of the treatment groups will be concealed from the statistical consultant to ensure blinding at the data analysis stage.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Dentistry, Mashhad University of Medical Sciences

Street address

no 88, abuzar ghaffari 31, ahmadabad

City

Mashhad

Province

Razavi Khorasan

Postal code

9176838569

Approval date

2025-06-07, 1404/03/17

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1404.040

Health conditions studied

1

Description of health condition studied
Patients with oral lichen planus
ICD-10 code
L43.9
ICD-10 code description
Lichen planus, unspecified

Primary outcomes

1

Description
Change in CFU count (Candida colony-forming units)
Timepoint
Assessments will be conducted before treatment, and at weeks 1, 2, and 4.
Method of measurement
Before treatment, the current status of oral lichen planus (location, size, severity of lesions, presence of pain and burning) and CFU count will be recorded. CFU sampling is performed using a sterile swab from the dorsal surface of the tongue. In general, CFU is expected to be positive in all patients, with values above 500 CFU/g

2

Description
Change in lesion severity based on Thongprasom criteria
Timepoint
Assessments will be conducted before treatment, and at weeks 1, 2, and 4.
Method of measurement
The Thongprasom scale is used to assess the severity of oral lichen planus lesions as follows:0: No lesion, normal mucosa/1: Mild white lines without erythematous area/2: White lines with atrophic area less than 1 cm/3: White lines with atrophic area greater than 1 cm/4: White lines with ulcerative area less than 1 cm/5: White lines with ulcerative area greater than 1 cm

3

Description
Change in pain and burning sensation based on the Visual Analog Scale (VAS)
Timepoint
Assessments will be conducted before treatment, and at weeks 1, 2, and 4.
Method of measurement
The Visual Analog Scale (VAS) is a straight line, usually 100 millimeters long, printed on a sheet of paper. It has two defined endpoints: "No pain" on the left end and "Worst imaginable pain" on the right end. The patient marks their current pain level on this line using a pen.

Secondary outcomes

1

Description
Assessment of adverse effects related to nanocurcumin use
Timepoint
same as primary
Method of measurement
The patient will report any unusual symptoms or discomfort (such as nausea, diarrhea, headache, or skin reactions) to the investigator. These events will be recorded in standardized Adverse Event Forms. During each follow-up visit (weeks 1, 2, and 4), the physician will assess vital signs, general health, and any possible adverse reactions.

Intervention groups

1

Description
Intervention Group: This group receives only nanocurcumin (Sinacurcumin capsules, 80 mg). The soft gelatin capsule contains nanomicelles of curcumin and is taken once daily after breakfast with sufficient water.Sinacurcumin capsules are produced under clean conditions (GMP) at Minoo Factory in Tehran using pure curcumin powder supplied by Sami Labs, and prepared by Dr. Jafari (a faculty member of the Pharmaceutics Department). Each package contains about 50 capsules, enough for a one-month course (30 capsules).Based on an animal study where pure curcumin was administered to mice at 200 mg/kg to control candidiasis with satisfactory results, the equivalent human therapeutic dose is calculated as 0.32 mg/kg. Considering an average weight of 70 kg, the required dose of pure curcumin for humans is approximately 22.4 mg (0.32 × 70 = 22.4).The prescribed dose in this study (one 80 mg capsule daily) provides nearly three times this amount per person, which is similar to the usual dose used in oral lesions such as mucositis and lichen planus. Currently, this dose is also prescribed daily for osteoarthritis and fatty liver disease. Moreover, the oral bioavailability of nanomicelle curcumin is approximately 100 times higher than the conventional form.The first session includes introduction and initial examination, followed by prescription and explanation of drug usage. Follow-up sessions are scheduled based on the patient’s needs, with no fixed time limits for the sessions.
Category
Treatment - Drugs

2

Description
Control group: **Control Group:**Patients in the control group receive the standard treatment regimen, consisting of 0.5 mg dexamethasone mouthwash (Abureyhan Pharmaceutical) and 100,000 units/mL nystatin suspension (Jaber Ibn Hayyan Pharmaceutical), taken three times daily with 5 mL each time for one month.The 0.5 mg dexamethasone mouthwash is used by rinsing 5 mL in the mouth and gently swishing it

around for 30 seconds to one minute to ensure contact with all areas. Patients are instructed not to swallow the solution and to avoid eating or drinking for at least 30 minutes afterward to maintain the medication's effectiveness.Nystatin 100,000 units/mL suspension is typically used orally to treat fungal infections of the mouth. The usual dosage is four times daily, holding 4 to 6 mL of the suspension in the mouth before swallowing or spitting it out.It is recommended to maintain a minimum interval of 30 minutes to 1 hour between the use of the two mouthwashes to allow each enough time to work effectively and to prevent drug interactions. This interval helps improve absorption and efficacy of the medications.The first session includes patient introduction, initial examination, drug prescription, and instructions on usage. Follow-up sessions are scheduled as needed without any fixed time limits.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad Dental School – Oral and Maxillofacial Diseases Research Center – Mashhad University of Medi

Full name of responsible person
Dr Toktam Zamani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Rasoul Sahebalam Deputy of Research and Technology, School of Dentistry

Street address
Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri 94)

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Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Helia Khosromanesh

Position
Student in general dentistry

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available