Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of anti inflammatory diet on clinical symptoms of Patients with oral Lichen Planus : Randomized clinical trial

Protocol summary

Study aim
Determination of the effect of an anti-inflammatory diet on clinical symptoms in patients with oral lichen planus (OLP)

Design
Clinical trial with control group, with parallel groups (diet and routine treatment group and routine treatment only group), single-blind, randomized, phase 3 on 60 patients. Randomized block stratification based on gender and allocation to two groups will be done using random blocks.

Settings and conduct
The trial will be conducted in the Department of Oral medicine, Tabriz Faculty of Dentistry. Patients with Oral lichen planus will be randomly assigned to two groups: receiving an anti-inflammatory diet and routine treatment, and a control group receiving routine treatment. Blinding of patients is not possible, but the evaluator investigating the outcomes will be blinded to the patient grouping. The pain level and clinical score of the patients will be determined and compared after 4 and 8 weeks.

Participants/Inclusion and exclusion criteria
Patients with a definitive diagnosis of OLP based on clinical and histopathological criteria, aged 18 to 65 years, with symptomatic erosive and ulcerative lesions with grades 4 and 3 according to the Thongprasom Score

Intervention groups
Intervention group: receiving anti-inflammatory diet + routine treatment (corticosteroid mouthwash) Control group: receiving routine treatment (corticosteroid mouthwash)

Main outcome variables
Clinical score based on Thongprasom scoring system; pain level using Visual Analog Scale (VAS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200108046050N2**
Registration date: **2026-07-16, 1405/04/25**
Registration timing: **prospective**

Last update: **2026-07-16, 1405/04/25**
Update count: **0**

Registration date
2026-07-16, 1405/04/25

Registrant information

Name
Katayoun Katebi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date
2027-03-20, 1405/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of anti inflammatory diet on clinical symptoms of Patients with oral Lichen Planus : Randomized clinical trial

Public title
Effect of anti inflammatory diet on Patients with oral Lichen Planus
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of OLP based on clinical and histopathological criteria Age 18 to 65 years Presence of symptomatic erosive and ulcerative lesions Ability to adhere to diet Involvement of lesions in buccal mucosa, anterior two-thirds of tongue, labial mucosa, gingiva, and hard palate (where mouthwash can come into contact with them) Disease severity based on Thongprasom Score grade 4 and 3
Exclusion criteria:
Taking immunosuppressive medications Having systemic diseases including diabetes, high blood pressure, cardiovascular and metabolic diseases, inflammatory bowel diseases Pregnancy or breastfeeding Consumption of alcohol or smoking On a vegetarian or other diet Presence of lesions in the pharynx, soft palate and back of the tongue that require systemic treatment due to lack of mouthwash contact
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be assigned to two intervention and control groups using a gender-stratified block randomization. Participants will first be divided into two groups: male and female. Then, within each group, they will be assigned to two groups using random blocks of variable size (4 and 6) and a ratio of 1:1. The randomization sequence will be generated by computer software. For allocation concealment, the method of sealed opaque envelopes which are numbered sequentially will be used. In this method, each random sequence is recorded on a card. Finally, the lids of the letter envelopes will be glued and placed inside a box. At the beginning of the registration of participants, according to the order of entry of eligible participants to study, one of the envelopes will be opened in order and the assigned group of the participant will be revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
The outcome assessor who will examine the patients will be blinded to the patient grouping and will record the clinical data in code form.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz faculty of dentistry, Golghasht street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2026-06-22, 1405/04/01
Ethics committee reference number
IR.TBZMED.REC.1405.206

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
Clinical score based on Thongprasom scoring system
Timepoint
Clinical score measurement at the beginning of the study (before the intervention) and 4, 8 weeks after starting routine medication and anti-inflammatory diet
Method of measurement
The largest lesion in the oral cavity is selected and its largest diameter is recorded using a sterile surgical ruler. The scoring method is as follows: Score 0: No lesion. Score 1: White striae with erythematous area < 1 cm2. Score 2: White striae with erythematous area > 1 cm2. Score 3: White striae with erosive area < 1 cm2. Score 4: White striae with erosive area > 1 cm2.

2

Description
Pain level based on visual analogue scale

Timepoint
Pain level measurement at the beginning of the study (before the intervention) and 4, 8 weeks after starting routine medication and anti-inflammatory diet

Method of measurement
Patients will be asked to mark a 10 cm line with the left end representing no pain and the right end representing the most severe pain possible.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Recipient of anti-inflammatory diet + routine treatment (Corticosteroid mouthwash). The intervention group will follow a standardized anti-inflammatory diet for 8 weeks. This diet is based on the principles of the Mediterranean-DASH modified diet and includes quantitative guidelines, a list of allowed/not allowed foods, and a weekly schedule. Participants must meet the following daily goals: 1. Fruits and vegetables at least: 5 units per day each unit = 80 g Minimum combination: three units of vegetables and 2 units of fruit 2. Whole grains at least: 3 units per day each unit: 1 slice of wholemeal bread (30 g) or ½ cup of rice 3. Chicken and fish and omega-3 at least: 2 servings per week (150–200 g per serving) 4. Oils Extra virgin olive oil: at least 2 tablespoons per day Prohibited: trans and industrial frying oils 5. Nuts and seeds 30 g per day (almonds, walnuts, hazelnuts) 6. Dairy 1–2 servings per day (preferably low-fat and without added sugar) Participants should minimize their intake of: Simple sugars <5% of daily calories, sugary drinks 0 to a maximum of 1 serving per week Fast food, maximum of 1 serving per month Processed meat, completely prohibited Red meat ≤ 1 serving per week (100–120 g) Fried foods, maximum of 1 serving per week Education and supportive intervention: In the initial education session, the principles of the anti-inflammatory diet will be taught and a list of allowed/not allowed foods will be given to patients in writing. A food portion size guide and a sample weekly meal plan will also be given to patients. To reduce implementation errors, a dietitian will be responsible for supervising patient education and monitoring their adherence. All recommendations will be standardized and uniform. Adherence to the intervention: A participant will be considered “adherent” when they meet at least 80% of the daily dietary goals. A phone call will be made every two weeks to monitor patient adherence.

Category
Rehabilitation

2

Description
Control group: Recipient of routine treatment (Corticosteroid mouthwash). Patients will use a full spoon of mouthwash containing 15 betamethasone ampules in Almg syrup every 8 hours.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Faculty of Dentistry

Full name of responsible person
Katayoun Katebi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Tabriz 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
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Full name of responsible person
Katayoun Katebi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The main outcomes of the study, including clinical scores and pain scores, in two groups and three time intervals will be published.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutes, doctors and dentists
Under which criteria data/document could be used
Use of the data for further research or meta analysis is

permitted.

From where data/document is obtainable

Katayoun Katebi 00984133355965 Department of oral medicine, Tabriz faculty of dentistry katebik@tbzmed.ac.ir

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

The applicant sends their request via email along with their introduction, and the information and data are sent to their email after reviewing their profile.

Comments