# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of the Effect of Gamma-oryzanol Mucoadhesive paste with Betamethasone Mouthwash and Betamethasone Mouthwash Alone on Clinical Manifestations and Pain Severity in Oral Lichen Planus Patients

## Protocol summary

**Study aim**

Comparison of the effect of gamma-oryzanol mucoadhesive paste along with betamethasone mouthwash and betamethasone mouthwash alone on clinical manifestations and pain intensity in patients with oral lichen planus

**Design**

Clinical trial, with a control group, with parallel groups, randomized, on 38 patients

**Settings and conduct**

It is a double-blind randomized trial study on 38 patients with oral lichen planus referred to Tabriz University of Medical Sciences Faculty of Dentistry in order to compare the effect of gamma-oryzanol with betamethasone mouthwash on the treatment of oral planus lichen. People are placed in two groups A and B based on a random sequence by a third person (other than the main researcher). The case group received gamma-oryzanol mucoadhesive along with betamethasone mouthwash and the control group received betamethasone mouthwash.

**Participants/Inclusion and exclusion criteria**

Entry criteria: definitive diagnosis of oral lichen planus based on clinical and histopathological findings of patients with at least one visible and measurable ulcerative or atrophic or reticular lichen planus lesion, absence of dysplasia, age over 18 years, absence of underlying disease Exclusion criteria: pregnancy and breastfeeding, uncontrolled diabetes, blood pressure and other underlying diseases Allergy to betamethasone mouthwash or gamma-oryzanol , use of drugs that cause lichenoid reaction or the presence of amalgam repair in the vicinity of the lesion, the presence of skin or other mucosal lesions, patients with oral candidiasis, viral infections, receiving treatment for oral lichen planus During the last 12 weeks

**Intervention groups**

Case: 19 patients who receive gamma-oryzanol mucoadhesive along with betamethasone mouthwash.
Control: 19 patients taking betamethasone mouthwash

**Main outcome variables**

Clinical score based on Thongprasom's scale, pain score using Visual Analogue Scale (VAS)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20250106064298N1**
Registration date: **2025-02-18, 1403/11/30**
Registration timing: **prospective**

Last update: **2025-02-18, 1403/11/30**
Update count: **0**

**Registration date**

2025-02-18, 1403/11/30

**Registrant information**

**Name**
Sara Hasan Nejad
**Name of organization / entity**
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Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-02-19, 1403/12/01

**Expected recruitment end date**

2025-11-22, 1404/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the Effect of Gamma-oryzanol Mucoadhesive paste with Betamethasone Mouthwash and Betamethasone Mouthwash Alone on Clinical Manifestations and Pain Severity in Oral Lichen Planus Patients

**Public title**

Effect of Gamma-oryzanol in Lichen Planus

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Definitive diagnosis of Oral Lichen Planus based on clinical and histopathological findings of patients with at least one visible and measurable ulcerative or atrophic or reticular Oral Lichen Planus lesion Patients who have not received immunosuppressive drugs Absence of dysplasia Absence of underlying disease Completeness of the file including demographic and clinical information

**Exclusion criteria:**

Allergy to betamethasone or gamma-oryzanol mouthwash There are only reticular lines in the patient's mouth and the lichen planus is painless The presence of uncontrolled diabetes Blood pressure and other underlying diseases that can interfere with participation and compliance with the study Immunosuppression Hepatitis (because corticosteroid suppresses the immune system and increases the likelihood of viremia) The use of lichenoid reaction drugs or the presence of amalgam repair in the vicinity of the lesion The presence of skin or other mucosal destruction lesions Patients with oral candidiasis Receiving treatment for oral lichen planus in the past 12 weeks Viral infections Pregnancy and breastfeeding

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **38**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After selecting eligible patients, randomization will be done by envelope method and divided into two groups with equal distribution of groups. Patients are matched in terms of age and sex, and the third researcher will perform randomization. A third investigator will not participate in any assessment during or after treatment. The study group (case or control) will be placed inside identical envelopes marked with consecutive numbers. Envelopes will be sealed until treatment begins.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Two drugs are prepared and assigned in the same form and in the same envelopes to the number of members of each group by a trained third person from number 1 to 38 for two groups so that none of the researchers and patients know about the contents of the package.

**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 University of Medical Sciences, Golgasht St., Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166616471

**Approval date**

2024-12-29, 1403/10/09

**Ethics committee reference number**

IR.TBZMED.REC.1403.773

## Health conditions studied

### 1

**Description of health condition studied**

Symptomatic oral lichen planus lesions

**ICD-10 code**

L43.8

**ICD-10 code description**

Other lichen planus

## Primary outcomes

**1**

**Description**
Clinical score based on Thongprasom's scale
**Timepoint**
At the beginning of the intervention, 4 weeks later, 8 weeks later, 12 weeks later
**Method of measurement**
The clinical score will be calculated based on Thongprasom's scale: grade 0 = no lesion / normal mucosa grade 1 = white striae / no erythematous area grade 2 = white striae with an atrophic area equal to or less than 1 cm2 grade 3 = white striae with area Atrophic more than 1 cm2 grade 4 = white stretch marks with erogenous area equal to or less than 1 cm2 grade 5 = white stretch marks with erogenous area more than 1 cm square meter

**2**

**Description**
Pain score using Visual Analogue Scale
**Timepoint**
At the beginning of the intervention, 4 weeks later, 8 weeks later, 12 weeks later
**Method of measurement**
Pain will be evaluated using the VAS (Visual Analogue Scale) scale, which includes a 10 cm horizontal line from 0 = no pain, to 10 = the most severe pain experienced, and the patient chooses a number based on the pain intensity.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: At the beginning, plastic base is prepared. This base is made of polyethylene and liquid paraffin, with the explanation that polyethylene is added to liquid paraffin at the rate of 5% by weight and it melts and dissolves by heating the paraffin. Then it is spread in a thin layer on cold metal plates. By cooling the plastic base, the base is formed. Gamma-oryzanol is added by geometrical method, that is, its small amounts are mixed with small amounts of base up to larger amounts in a mortar. Its larger amounts are put under a mechanical stirrer to ensure the uniformity of gamma-oryzanol distribution in the base. In the next step, the components of the adhesive mucus, i.e. pectin, gelatin and sodium carboxymethyl cellulose, are added to the base with a ratio of one third each and their total ratio to the base with an equal ratio using the geometrical addition method under a mechanical stirrer. Care should be taken to ensure that water does not enter the formulation at all stages. It means to use completely dry dishes. It is better to completely dehydrate these mucous adhesive materials, i.e. pectin, gelatin and sodium carboxymethyl cellulose, before adding them to the formula for 1 day in a 60 degree oven. The prepared formulation is filled in tubes and their containers are closed and stored in a dry environment, preferably a desiccator, until use by the patient. After brushing and then using betamethasone mouthwash, patients will receive gamma-oryzanol adhesive mucus for 8 weeks. Mouthwash followed by adhesive mucus will be used three times a day. Patients will be followed up 4, 8 and 12 weeks later. The evaluated parameters will include clinical score based on Thongprasom's scale and pain using VAS. Patients will be taught how to use drugs.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Patients in this group will use the standard routine treatment regimen. Betamethasone mouthwash is used for 8 weeks after brushing. Mouthwash will be used three times a day. Patients will be followed up 4, 8 and 12 weeks later. The evaluated parameters will include clinical score based on Thongprasom's scale and pain using VAS. Patients will be taught how to use drugs.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Tabriz Faculty of Dentistry
**Full name of responsible person**
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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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**Web page address**
https://researchvice.tbzmed.ac.ir

**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**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
Maryam Kooh Soltani

**Position**
Associate Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Dentistry

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
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Sara Hasan Nejad

**Position**
Student

**Latest degree**
A Level or less

**Other areas of specialty/work**
Dentistry

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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**

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

**Title and more details about the data/document**

Participant data file, information related to the main outcome

**When the data will become available and for how long**

18 months after the study

**To whom data/document is available**

Data is published

**Under which criteria data/document could be used**

In case of citation

**From where data/document is obtainable**

Sara hasannejad, sarahasannejad9801@gmail.com

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

By communicating with the person in charge of the update

**Comments**