

# Treatment effectiveness of triamcinolone oral paste and amlexanox oral paste in oral lichen planus

<b>Submission date</b> 11/04/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/12/2023	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Oral lichen planus is an inflammatory condition that affects the mucous membranes inside the mouth. There is no specific curative drug or treatment for oral lichen planus and in most cases management relies on corticosteroids for the relief of symptoms. There is research ongoing to find alternative topical therapeutics to corticosteroids. This study aims to compare the effectiveness of topical Amlexanox 5% oral paste and triamcinolone acetonide 0.1% paste in the treatment of oral lichen planus.

### Who can participate?

Patients aged 18 to 70 years with oral lichen planus

### What does the study involve?

Participants are randomly allocated to be treated with either topical amlexanox paste or triamcinolone acetonide paste. The treatment continues for 1 month with three times daily drug application.

### What are the possible benefits and risks of participating?

Both the corticosteroid drug and amlexanox when used in early or mild stages of oral lichen planus can arrest disease progression to severe forms and avoid the use of systemic corticosteroids and immunomodulators. The selected topical drugs have a high safety profile, favourable patient compliance and no systemic side effects.

### Where is the study run from?

D Y Patil University, School of Dentistry (India)

### When is the study starting and how long is it expected to run for?

November 2021 to December 2023

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Biswadip Shyam, biswadipshyam@gmail.com

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Biswadip Shyam

### ORCID ID

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

IREB/2021/OMR/09

## Study information

### Scientific Title

Comparative efficacy of topical amlexanox 5% oral paste and triamcinolone acetonide 0.1% oromucosal paste in the treatment of oral lichen planus – a randomized control trial

### Study objectives

Amlexanox oral paste has been compared with triamcinolone acetonide 0.1% oromucosal paste (considered as the gold standard therapy) in the treatment of oral lichen planus.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 26/11/2021, Institutional Research & Ethical Board (D Y Patil University School of Dentistry, Navi Mumbai, Maharashtra, India; +91 (0)9029999633; dentistry@dypatul.edu), ref: IREB/2021/OMR/09

## Study design

Interventional double-blind parallel-group randomized control trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Oral lichen planus

## Interventions

30 patients with oral lichen planus were included in the study. After clinical diagnosis and histopathological confirmation, the selected patients were divided into two groups – group A and group B, through a randomization process (chit method [lottery] followed by dispatch in opaque envelopes [allocation concealment]). Patients in group A received 0.1% triamcinolone acetonide oro-mucosal paste (n = 15) and patients in group B received 5% amlexanox oral paste (n = 15) after allocation concealment, for 1 month and their responses to the treatment were recorded.

## Intervention Type

Drug

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Triamcinolone acetonide 0.1%, amlexanox 5%

## Primary outcome(s)

Size of the lesion measured using self-modified Thongprasom sign scoring system for oral lichen planus, at baseline (day 0) and days 15, 30 and 45

## Key secondary outcome(s)

1. Pain intensity measured using the visual analogue score (VAS) at baseline (day 0) and days 15, 30 and 45
2. Clinical erythema measured using Clinician Erythema Assessment grading scale at baseline (day 0) and days 15, 30 and 45
2. Incidence of adverse drug reactions (if reported) during the treatment course
3. Quality of life assessed using the Chronic Oral Mucosal disease questionnaire (COMDQ) after treatment completion

## Completion date

28/12/2023

## Eligibility

### Key inclusion criteria

1. Patients diagnosed with oral lichen planus
2. Age range 18 to 70 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

30

**Key exclusion criteria**

1. Patients with a history of malignancy, immunocompromised diseases, metabolic diseases, pregnancy or breastfeeding, systemic viral infections, other red and white lesions
2. Undergoing systemic therapy that may interfere with disease prognosis
3. Active therapy for oral lichen planus
4. Known allergies to the study drugs

**Date of first enrolment**

10/01/2022

**Date of final enrolment**

28/12/2022

**Locations****Countries of recruitment**

India

**Study participating centre**

**D Y Patil University**

Department of Oral Medicine & Radiology, School of Dentistry

Nerul east, sector 7

Navi Mumbai

India

400706

# Sponsor information

## Organisation

D.Y. Patil University

## ROR

<https://ror.org/045qb5273>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Biswadip Shyam (biswadishyam@gmail.com).

## IPD sharing plan summary

Available on request