

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

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Submission date 11/04/2023 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 25/04/2023 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 05/12/2023 | Condition category 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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

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