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

Submission date
11/04/2023

Recruitment status
No longer recruiting

Registration date
25/04/2023

Overall study status
Completed

Last Edited
05/12/2023

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 (conisidered 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

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure
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

Secondary outcome measures

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

Overall study start date
20/11/2021

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

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
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India
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Sponsor information

Organisation
D.Y. Patil University

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Sponsor type
University/education

Website
http://www.dypatil.edu/

ROR
https://ror.org/045qb5273

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
20/06/2024

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