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An early phase clinical trial to investigate the safety of imiquimod oromucosal films in treating patients with oral lesions arising from leukoplakia

Submission date
09/05/2026

Recruitment status
Not yet recruiting

Registration date
11/08/2026

Overall study status
Ongoing

Last Edited
11/08/2026

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This is the first clinical study utilising imiquimod (IMQ) [an already approved drug] in this current pharmaceutical form (drug-eluting film), and has been designed to assess safety and acceptability when applied to oral mucosa. The study is proposed in patients rather than healthy volunteers to give more representative information on the usage in the patient population for which it is intended, and to assess permeation in damaged mucosa and dysplastic lesions of the mouth.

Who can participate?
Patients with a lesion that is accessible, measurable (at least 100 mm2), amenable to clinical photography and located in the oral cavity. Histology from tissue biopsy records (obtained within the last 6 months) will confirm the dysplasia diagnosis.

What does the study involve?
In this within-patient study, participants will initially receive a placebo film for application to an oral lesion for one hour every day for 7 days, followed by an IMQ film for a further 14 days. Clinical assessments, and biopsies of the lesion will be undertaken to assess improvements of the lesion, blood samples for pharmacokinetic analysis and QoL questionnaires will be collected to assess patient experience.

This is proposed as an open-label, single-centre study, with the intention to enroll 25 patients (allowing for 20% dropout). Following Screening (Visit 1) the study will involve a Baseline assessment (Visit 2, Day 1) where the attending clinician will provide instructions and demonstrate how to apply the biofilm. This clinic is then followed by three 'On' treatment visits during which the placebo film (1-week, Day 1-8) followed by active IMQ treatment phase 2-weeks (Visits 3-5 on Days 8, 15, 22) are performed. Finally, a further visit 1 month following

completion of treatment will be performed (Follow-Up Visit 6). Proposed clinical and pharmacokinetic assessments will be performed at the clinic centre during visits, however patients will be allowed to apply films themselves at home.

What are the possible benefits and risks of participating?
In general, the risks involved for participants are minimal. IMQ has been used for many years with no evidence for long-term toxicity. Minor risks arise associated with IMQ, including non-severe irritation (mucositis) and systemically from fever or chills. All are generally reversible upon stopping treatment for short periods. Risks of AEs are reduced compared to the use of off-label creams, as the film preparation is loaded with only 50% of the IMQ drug substance compared to cream formulations. Moreover, data in non-clinical models indicate reduced potential for drug permeation through tissue into the systemic circulation from film.

Risks to the participants of the study are also minimised with specific training and monitoring of subjects to ensure proper use of the product and associated rigorous daily monitoring for issues with safety during the initial stages of treatment.

Where is the study run from?
Mucora Therapeutics Ltd, UK.

When is the study starting and how long is it expected to run for?
August 2026 to September 2027.

Who is funding the study?
Mucora Therapeutics Ltd, UK.

Who is the main contact?
Mr David Fleet, CEO of Mucora Therapeutics Ltd, davidfleet@manentia.co.uk.

Contact information

Type(s)
Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
1014103

Sponsor's protocol code number
MUC01

Study information

Scientific Title
A phase I/IIa safety and acceptability investigation of an imiquimod (IMQ) oromucosal film [0.1575mg/cm2] in patients with oral leukoplakia (OL)

Study objectives
To investigate the safety profile and acceptability of the Imiquimod Oromucosal film, following daily use by participants.

Secondary objectives of the trial include:
* Investigation of the extent of local tissue and systemic absorption of imiquimod through pharmacokinetic analysis
* Pharmacodynamic evaluation of biopsy tissue to assess potential immunohistopathology markers to investigate imiquimod activity.
* Quality of life of patients treated with imiquimod.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/07/2026, London - London Bridge Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; -; londonbridge.rec@hra.nhs.uk), ref: 26/LO/0417

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Sequential

Purpose
Treatment, Safety

Study type(s)
Efficacy, Safety, Treatment, Other

Health condition(s) or problem(s) studied
Oral leukoplakia, painless white or grey patches in the mouth that cannot be wiped away. It is considered a potentially malignant disorder and can be associated with smoking and other irritants.

Interventions
Open-label investigation (no randomisation)
Daily administration for 1 hour of an Imiquimod Oromucosal Film 0.1575mg/cm2 affixed to a single dysplastic lesion in the mouth cavity for a total of 3 weeks of treatment (1 week placebo then 2 weeks imiquimod). Follow up 1 month thereafter.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Imiquimod Oromucosal Film 0.1575mg/cm2 [Imiquimod]

Primary outcome(s)
1. Frequency and severity of local and systemic adverse events from the oromucosal film measured using adverse events data captured from screening through until final visit 6, one month post-completion of treatment, and evaluated at one time point at the end of the study

2. Participant acceptability measured using a questionnaire concerning the use and application of the film at 3 weeks of treatment with the placebo and imiquimod oromucosal film

Key secondary outcome(s)

Completion date
01/09/2027

Eligibility

Key inclusion criteria
1. Men or women with a diagnosis of mild, moderate or severe oral leukoplakia (OL)
2. 18 years of age or over

3. Active OL present and not treated for at least one month (but less than 6 months)
4. Active disease with one or more OL lesions affecting gingiva, tongue, vestibular mucosa or hard palatal mucosa based on clinical and biopsy evidence
5. Involvement in study fits with planned treatment strategy (Low/Medium risk: Watch and wait only - no action planned; or High risk: Elective surgery date schedule fits with trial requirements.
6. General health status acceptable for participation for up to 2 months (3-week treatment period, plus 1 month follow-up) in clinical trial.
7. Able to easily apply oromucosal films themselves
8. Signed informed consent by participant prior to the initiation of any study specific procedure.
9. Good level of understanding of spoken and written English
10. Women of child-bearing potential must have a negative serum pregnancy test at screening and must be practicing adequate, medically acceptable methods of birth control.
11. Women of non-child bearing potential must be in a menopausal state for at least a year, or had a hysterectomy, a bilateral oophorectomy or be clinically diagnosed infertile.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Prohibited Associated Conditions:
1. Any participant with previous diagnosis of synchronous or metachronous oral squamous cell carcinoma (OSCC)
2. Any participant with hypersensitivity (allergies) to either Imiquimod or excipients of the oromucosal film
3. Any participant with pre-existing cardiovascular issues, reduced haemataological reserve, compromised immunity, inflammatory conditions, autoimmune or organ transplant situations which may impact imiquimod use.
4. Any other chronic co-morbidity which is not controlled by appropriate medication.
Prohibited medications:
5. Any OL treatment in the last one month
6. Any systemic immunosuppressive agent in the last one month
7. Any treatments for the relief of oral irritation in the last one month (e.g. Anbesol (2% lidocaine)).
8. Any investigational drug treatment (i.e. clinical trial involvement) in the last one month.
General Exclusions:
9. Any history of cutaneous or systemic medical illness or psychiatric disease which will put

participant at risk or interfere with assessments
10. Any known HIV or Hepatitis B or C positive conditions
11. Any vaccination with herpes zoster or any live virus in the last one month
12. Hospitalisation or change of chronic concomitant medication in the last one month. Any planned hospitalisation during trial involvement.
13. Symptoms of severe cardiovascular disease or heart related problems
14. Drug or alcohol abuse.
15. Women who are pregnant or nursing
16. Any condition which in the opinion of the investigator makes the participant unsuitable for inclusion.

Date of first enrolment
31/08/2026

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oral Medicine, School of Dentistry (Clinical Research Facility), University of Liverpool
Pembroke Place
Liverpool
England
L3 5PS

Sponsor information

Organisation
Mucora Therapeutics Ltd

Funder(s)

Funder type

Funder Name
Mucora Therapeutics Ltd

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data will be made available upon reasonable request to the sponsors, David Fleet, CEO of Mucora Therapeutics, davidfleet@manentia.co.uk, for research purposes once the trial is completed and results are published. Requests should be submitted by email, detailing reasons for use and a signed data confidentiality agreement. Consent is available for all individual Case Report Form data, which is stored in a secure cloud-based server. Access will be provided by username and password to the SAS datasets.

IPD sharing plan summary
Available on request