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Treatment of recurrent aphthous stomatitis with an intra-oral patch

Submission date 13/08/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 14/08/2024	**Overall study status** Completed	
Last Edited 13/08/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Recurrent aphthous stomatitis (RAS) is the presence of small, painful sores inside the mouth. The treatments of RAS currently available on the market are primarily aimed at alleviating pain and facilitating healing to reduce symptoms. A variety of local therapies have been used, but those studies have low or very low evidence of efficacy. There are currently a variety of systemic treatments on the market, based mainly on corticosteroids, other immunosuppressive agents and antimicrobial agents. These treatments (such as pentoxifylline, colchicine, dapsone and thalidomide) should be given with caution due to the potential for adverse events.
Thus, there is a need for improved therapy for individuals with RAS, both in terms of effectiveness, safety, and simplicity. In this clinical trial, a dehydrating mucoadhesive oral patch will be compared with standard care (no treatment) in research subjects with recurrent aphthous stomatitis (RAS). The objective is to evaluate the effectiveness and safety of a dehydrating oral patch in subjects with RAS.

Who can participate?
Patients aged 12-70 years who have had at least two RAS episodes during the last 6 months

What does the study involve?
Participants will be randomly allocated to active treatment and receive 1-3 patches depending on the number of ulcers. The remaining participants will not be treated (standard care). The patch/patches will be applied by a dentist or dental hygienist. The pain will be estimated by the participants using an NRS, which means that they choose a number between 0 (no pain) and 10 (worst possible pain). The participants will estimate their pain before application and after 10 minutes after application or after non-application of the patch. This pain assessment will be repeated at the Clinic after 1 hour. The pain will then be assessed at different time points (2, 4, 6 and 8 hours) following application/no application of the patch. This data will be collected together with the quality of life data through a diary which the participants will be asked to send in the day after the primary visit.

What are the possible benefits and risks of participating?
The benefit of participating is instant relief of pain caused by RAS. In this clinical investigation, the patch will be applied by a dentist or dental hygienist. Due to the strong adhesive effect of

the patch, the risk of aspiration of the patch is minimal. Even if the patch is accidentally lost during application, the chance that the patch will attach to the oral mucosa (mouth lining) before it reaches the lungs is significant.

Where is the study run from?
Mucocort AB (Sweden)

When is the study starting and how long is it expected to run for?
May 2023 to June 2025

Who is funding the study?
Umeå Biotech Incubator (Sweden)

Who is the main contact?
Mats Jontell, mgjontell@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
CIV-ID 23-12-045096

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RAS01-M045A

Study information

Scientific Title
A randomized, parallel-group, comparative investigation of M045A in the treatment of recurrent aphthous stomatitis

Acronym
Aphthastop

Study objectives
The null hypothesis (H0) for the primary endpoint is that M045A (intra-oral patch) is not superior to no treatment in reducing pain after 10 minutes following application/no application of M045A. H1 for the primary endpoint is that M045A is superior to no treatment in reducing pain after 10 minutes following application/no application of M045A.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/04/2024, Swedish Ethical Review Authority (Box 2110, Uppsala, 750 02, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: Dnr 2024-02056-01

Study design
Randomized parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Dental clinic

Study type(s)
Quality of life, Treatment, Safety

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Recurrent aphthous stomatitis (RAS)

Interventions
The participants will be invited through an invitation letter and asked to contact the site when they have prodromal symptoms or when they present with ulcers. The participants referred to the study site may also be asked to participate as part of their primary visit if they present with ulcers. All participants will be subjected to an ordinary oral medicine examination including questions about their oral and medical health. After RAS has been established as the diagnosis, the participants will be informed about the clinical investigation by the investigator (oral and written). Informed consent needs to be collected before any investigation-specific activities can

take place. Once the consent form has been signed, the PI or delegated site staff will be responsible for the completion of a CRF for each of the 50 research subjects. The CRF will include participant details (initials and subject ID), medical history, visit details and dates, questionnaires, any related adverse events (AEs), any device deficiencies and details of withdrawal from the study if appropriate.

Participants will be randomized to active treatment and receive 1-3 patches depending on the number of ulcers. The remaining participants will not be treated (standard care). The patch /patches will be applied by a dentist or dental hygienist. The pain will be estimated by the participants using an NRS, which means that they choose a number between 0 (no pain) and 10 (worst possible pain). The participants will estimate their pain before application and after 10 minutes after application or after non-application of the patch. This pain assessment will be repeated at the Clinic after 1 hour. The pain will then be assessed at different time points (2, 4, 6 and 8 hours) following application/no application of M045A. This data will be collected together with the quality of life data through a diary which the participants will be asked to send in the day after the primary visit.

Randomization:
Stratification by age and pain (age; ≥12 years - ≤18 years, >18 years; pain Numeric Rating Scale [NRS] 4-7, >7).

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase III

Drug/device/biological/vaccine name(s)
Intra-oral patch (medical device)

Primary outcome measure
Pain intensity measured using a numeric rating scale (NRS) at baseline and 10 minutes

Secondary outcome measures
1. Pain intensity measured using a NRS at baseline and 1, 2, 4, 6, and 8 hours
2. Inadequacy of the medical device with respect to its identity, quality, durability, reliability, safety or performance will be reported as a device deficiency without unnecessary delay to the Sponsor by using the device deficiency form. It is the PI’s responsibility to record every observed device deficiency together with an assessment. The Sponsor will review all device deficiencies and determine and document in writing whether they could have led to a Serious Adverse Event (SAE).
3. Quality of life measured using EQ-5D-5L at 2 hours
4. Quality of life measured using Oral Health Impact Profile-14 (OHIP-14) scores at 2 hours

Overall study start date
23/05/2023

Completion date

01/06/2025

Eligibility

Key inclusion criteria
1. Males or females, 12 -70 years of age
2. ≥2 RAS episodes over the past 6 months
3. ≤3 wounds at the time of the study visit
4. The diameter of the wounds <10 mm
5. The pain from RAS ≥4 on the NRS
6. The subjects should have the ability and willingness to provide informed consent

Participant type(s)
Patient

Age group
Other

Lower age limit
12 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Treated at any time with mucosal topical, oral, or systemic corticosteroids less than 1 month prior to screening.
2. On TNF-alpha modulating drugs or DMARDs less than 1 month prior to screening
3. Suffering from any oral mucosal disease other than RAS at the time of enrollment
4. Any other condition as judged by the investigator to make the investigation inappropriate
5. Current alcohol or substance abuse
6. Participating in any other clinical trial or have participated in any other clinical trial within 1 month prior to the study start

Date of first enrolment
01/09/2024

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
Sweden

Study participating centre
OC Avenyn
Viktor Rydbergsgatan 1A
Göteborg
Sweden
411 34

Study participating centre
OC Särö
Furubergsvägen 3
Särö
Sweden
429 41

Sponsor information

Organisation
Mucocort AB

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Sponsor type
Research organisation

Website
https://www.ubi.se/contact/

Funder(s)

Funder type
Industry

Funder Name
Umeå Biotech Incubator

Results and Publications

Publication and dissemination plan
Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Intention to publish date
01/11/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to results publication.

IPD sharing plan summary
Published as a supplement to the results publication