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# A controlled study investigating the effect of Aloclair PLUS on pain caused by mouth ulcers

**Submission date**
23/07/2021

**Recruitment status**
Stopped

**Registration date**
05/08/2021

**Overall study status**
Stopped

**Last Edited**
20/11/2023

**Condition category**
Oral Health

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

## Plain English summary of protocol

Background and study aims
The aim of this study is to find out the effect Aloclair PLUS products have on pain caused by aphthous mouth ulcers in healthy adults. Aphthous mouth ulcers are a common condition; they are painful, round or oval ulcers confined to the mouth. The current treatment of mouth ulcers is to avoid known triggers (e.g., hard toothbrushes, spicy food) and to use saline (salt water) mouthwashes or medication (including protective gels/pastes and local anaesthetic (numbing) pain relief products). Aloclair PLUS is a barrier-forming application that comes in the form of a gel, a spray, a mouthwash and a patch. The products do not contain pharmaceutically active ingredients (medicine). The barrier protects the mouth ulcer from food and drink that can cause mouth ulcer pain. Aloclair PLUS is a registered medical device with a 'CE mark' which means it has been authorised for the treatment of mouth ulcers by a notified body and will be used within its authorisation for the purposes of this study. The main aim of this study will be to see if treatment of mouth ulcers with Aloclair PLUS provides pain relief when compared to the saline solution (salt water). The researchers will also assess how quickly any pain relief is experienced after using the device, how long any pain relief lasts and if Aloclair PLUS helps with healing.

Who can participate?
Healthy volunteers aged 18 years or older who have a painful mouth ulcer that began no more than 48 hours prior to screening and is between 2 mm and 10 mm wide (no more than 6 mouth ulcers)

What does the study involve?
This study has three stages:
1. Screening and enrolment (Day 1)
2. A treatment period (Days 1-4)
3. A follow-up visit (Day 5)
During stage one a doctor will carry out a physical examination and will examine participants' mouths' and measure the size of the mouth ulcer(s). Mouth ulcer size will also be measured on day 5. Participants will be asked to provide a urine sample at screening and follow up visits to check for use of drugs of abuse. Females of pre-menopausal age will have a pregnancy test performed. Breath tests will be performed to measure the amount of carbon monoxide and indicate if the participant smokes. The study doctor/dentist or nurse will also collect information

on any medicines taken by the participants, including vitamins and herbal supplements. Eligible participants will receive either one of the four Aloclair PLUS applications (gel, spray, mouthwash or patch) or the salt water/saline mouthwash. Pain will be recorded on a visual analogue scale. Participants will be asked to complete this scale several times on Day 1 both before and after swilling orange juice around their mouth. Pain records will be recorded in a diary. A different type of scale will be used to measure pain scores after eating and drinking at the end of Days 2, 3 and 4 – participants will be asked to rate pain as “None”, “Mild”, “Moderate”, “Severe” or “Very Severe.”

What are the possible benefits and risks of participating?
Participants will have more tests and procedures if they take part in the study, compared to standard dental visits. On Day 1 of the study participants are required to consume orange juice which may act as an irritant to ulcers. There is no guarantee that participants will benefit from using Aloclair PLUS products. At the end of the study participants will be given four 2 ml sachets of Aloclair PLUS gel to take home. There are currently no known side effects of Aloclair PLUS and it is not known to interact with medicines. Anaphylactic or serious allergic reactions have not been reported with Aloclair PLUS. There is a very small chance that participants may experience a serious allergic reaction to Aloclair PLUS therefore participants will be monitored for 30 minutes after the first study treatment application. Aloclair PLUS can be used during pregnancy and breastfeeding but pregnant or breastfeeding women will not take part in the study.

Where is the study run from?
Alliance Pharmaceuticals (UK)

When is the study starting and how long is it expected to run for?
May 2020 to June 2022

Who is funding the study?
Alliance Pharmaceuticals (UK)

Who is the main contact?
1. Dr Grace Evans (Medical Affairs Manager)
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2. Stephanie Brien (Scientific Advisor)
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# Contact information

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
ALLIANCE-246-UKR/ALO401

## Study information

### Scientific Title
Pain relief of mouth ulcers with a barrier-forming gel, mouthwash, spray and patch containing hyaluronic acid: a prospective, randomised, controlled study versus standard of care (saline mouthwash)

### Study objectives
Subjects treated with any Aloclair PLUS product will have a significant reduction in pain scores versus baseline, as compared with a control (0.9% saline solution)

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. Approved 29/04/2021, Ethics Committee at Municipal Non-Profit Enterprise “Consultative and Diagnostics Centre” of Desnianskyi District in the City of Kyiv (81/1 Zakrevskogo str., Kyiv, 02232, Ukraine; +38 (0)44 533 20 68; lec-crp@ukr.net), ref: 29.04.2021 No. 8/1

2. Approved 11/06/2021, Ethics Committee at the Limited Liability Company “Medibor” (2 Putiatynsky Square, Zhytomyr city, 10002; +38 (0)67 357 97 96; ethics@medibor.com), ref: 11.06.21 No 26
3. Approved 23/06/2021, Ethics Committee at Communal Non-Profit Enterprise “Kherson City Clinical Hospital named after Ye.He.Karabelesh” (22/1 Ushakova prospekt, Kherson, 73003, Ukraine; +38 (0)552 22 59 74; seaclinic@ukr.net), ref: 23.06.2021 No. 13-СП

## Study design
Prospective randomised controlled open-label study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
No participant information sheet available

## Health condition(s) or problem(s) studied
Aphthous mouth ulcers

## Interventions
This is a prospective, randomised, controlled, parallel-group open-label study, across two centres, investigating pain relief of aphthous ulcers (AU) with a barrier-forming gel, mouthwash, spray and patch contacting hyaluronic acid.

Consenting subjects will be screened on the day of enrolment. Those subjects who meet the enrolment criteria will be randomised to one of five arms (spray, mouthwash, gel, patch or SOC) in a ratio of 1:1:1:1:2. Following baseline assessments subjects will apply the device or control once. After 30 minutes’ observation they will be discharged to continue stimulus-induced pain assessments, at home, up to 8 h post-application. Subjects will use the randomised device or control in an ad hoc manner (up to four times per day) on Days 2–4 before returning to the clinic for a follow-up visit on Day 5.

Due to the physical differences between the five devices this is an open-label study.

All subjects will be randomly allocated via a block randomisation list with randomised block sizes which will be generated using a web-based random generator program (https://www.sealedenvelope.com/). At the screening visit (Visit 1) the Principal Investigator, or authorised designee, will add the subject identifier to the list in chronological order and will determine which coded treatment the subject will receive.

The list of randomisation numbers will be generated by an independent statistician to ensure intervention assignment is unbiased and concealed from the subjects and the Investigator/study site staff.

### Intervention Type
Device

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Aloclair PLUS Gel, Aloclair PLUS spray, Aloclair PLUS mouthwash, Aloclair PLUS patch

### Primary outcome measure
Overall pain as determined by the log area under the curve (AUC) of 10 cm visual analogue scale (VAS) pain scores measured over all stimulated time points (after 1 h) on Day 1 combined with overall pain scores from Days 2, 3 and 4

### Secondary outcome measures
1. The log AUC pain scores as measured by 10 cm VAS from Day 1 (0 to 8 h) only
2. Percentage reduction in unstimulated AU pain as measured by 10 cm VAS - calculation of baseline pain and pain at 5 and 30 minutes. A reduction of 20% will be classed as clinically important
3. Time stimulated pain relief (as measured by 10 cm VAS) is maintained at ≥20% from baseline scores: change in baseline score from baseline to 1, 2, 3, 4, 5, 6, 7 and 8 h
4. Pain when eating and drinking as measured by a Likert scale at the end of Days 2–4
5. Healing of lesion assessed by the clinician as healed, partially healed or unchanged at baseline and Day 5
6. Safety of devices as determined by reported adverse events during the study period
7. Stinging sensation upon first application measured using a rating out of 10 on site at first application

### Overall study start date
28/05/2020

### Completion date
30/06/2022

### Reason abandoned (if study stopped)
War in Ukraine

## Eligibility

### Key inclusion criteria
1. Able and willing to provide written informed consent and comply with study procedures
2. Healthy, male or female subjects aged ≥18 years old
3. Have an AU that began no more than 48 h prior to screening and is ≥2 mm and ≤10 mm in diameter
4. Have not more than six AU

5. Have a pain score ≥5.0 on the VAS at Screening without stimulus being applied
6. Fluent in the language of the study site and able to read in this language
7. Using a form of contraception with at least a 98% success rate when used correctly

## Participant type(s)
Patient

## Age group
Adult

## Lower age limit
18 Years

## Sex
Both

## Target number of participants
246

## Total final enrolment
52

## Key exclusion criteria
1. Have a known disorder or situation that causes mouth ulcers (including but not limited to connective tissue disorders and orthodontic devices)
2. Have a known allergy or known history of hypersensitivity to the components of the test device and/or related compounds
3. Clinically relevant abnormal medical history or physical findings at Screening that could interfere with the safety of the subject or objectives of the study
4. Have an oral disease, other than AU, that could interfere with the study
5. Have had oral surgery performed within 3 months prior to Screening
6. Have started taking medicines or using medical devices for the treatment of the outbreak of this AU
7. Ongoing pharmacological or device treatments that may interfere with the study (including but not limited to the use of herbal treatments, analgesics, antibiotics, and anti-inflammatories)
8. Use or intention to use any other topical treatments in the oral cavity or on the gums during the course of the study that might affect the study
9. Female subjects who are pregnant or breastfeeding
10. Female subjects who intend to conceive during the study
11. Drink more than 14 units of alcohol per week (female subjects) or more than 21 units per week of alcohol (male subjects) or who are not willing to abstain from alcohol during the period of the study
12. Do the following: smoke cigarettes, e-cigarettes, cigars or pipe, chew tobacco, use snuff or have used any of the aforementioned items within the last 3 months
13. Have a history of using drugs of abuse or have a positive test for drugs of abuse at the Screening visit
14. Subjects who, in the opinion of the Investigator, are not suitable for enrolment for another reason

## Date of first enrolment
08/11/2021

**Date of final enrolment**
25/06/2022

# Locations

**Countries of recruitment**
Ukraine

**Study participating centre**
**Municipal Non-Profit Enterprise “Consultative and Diagnostics Centre” Oo Desnianskyi District in the City of Kyiv**
81/1 Zakrevskogo str
Kyiv
Ukraine
02232

**Study participating centre**
**“Medibor” LLC**
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**Study participating centre**
**Communal Non-Profit Enterprise “Kherson City Clinical Hospital named after Ye.He.Karabelesh”**
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# Sponsor information

**Organisation**
Alliance Pharmaceuticals (United Kingdom)

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Avonbridge House
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**Sponsor type**
Industry

**Website**
http://alliancepharmaceuticals.com/

**ROR**
https://ror.org/001zd1d95

# Funder(s)

**Funder type**
Industry

**Funder Name**
Alliance Pharmaceuticals Ltd

# Results and Publications

**Publication and dissemination plan**
No publication planned at this stage.

**Intention to publish date**

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are not expected to be made available. Alliance does not wish to share individual participant data for data protection reasons. Alliance has contracted a third-party CRO to conduct the trial across three sites. During the study individual participant data will be collected in a case report form (CRF) at each of the three sites. The Investigator of each site and the head of the medical institution (where applicable) agree to allow the monitor, sponsor-appointed auditors and regulatory inspectors direct access to all relevant documents. Following closure of the study, the Investigator of each site or head of the medical institution (where applicable) will maintain all site study records in a safe and secure location.

**IPD sharing plan summary**
Not expected to be made available