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Comparison of three laser settings in the treatment of oral canker sore

Submission date	Recruitment status	[_] Prospectively registered
30/06/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/07/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2023	Oral Health	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
An aphthous ulcer, also known as a canker sore, is a common type of painful sore that forms inside the mouth. It appears as a round or oval lesion with a white or yellowish center and a red border. Aphthous ulcers can be quite uncomfortable and can make it difficult to eat, drink, or speak.
Laser treatment has been used as an alternative or adjunctive therapy for aphthous ulcers. The procedure involves the use of a laser beam to target and treat the affected area. The laser energy is applied to the ulcer, which helps promote healing and alleviate symptoms.
This study aimed to compare three types of laser in the treatment of aphthous ulcers.

Who can participate?
Adults from age 20-40 years having one or more aphthous ulcers.

What does the study involve?
Participants will be randomly allocated to receive one of three types of laser treatment or inactivated laser as a placebo. Assessment of pain, acceleration of healing, redness, patient satisfaction with treatment and recurrence.

What are the possible benefits and risks of participating?
Participants will have less pain sensation, acceleration of healing as well as improved quality of life. These types of lasers are safe and cause no harm to patients, regardless of their age and health condition.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
June 2019 to December 2022

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr. Esra'a AlHerafi, esraa.herafi.94@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3331

Study information

Scientific Title
A comparative study among three different wavelengths of low level laser on recurrent aphthous ulceration management

Study objectives
Studies suggested that low-level laser therapy is a suitable alternative or adjunct treatment option for recurrent aphthous ulcers. However, more clinical trials are required to be conducted to compare the efficacy of different wavelengths in order to ascertain their efficacy in the clinical setting

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/09/2019, Damascus University (Rector Baramkeh, Damascus, 3331, Syria; +963 555063806; info@damascusuniversity.edu.sy), ref: 3331

Study design
interventional single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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

Study type(s)
Treatment, Efficacy

Participant information sheet
See additional files (in Arabic)

Health condition(s) or problem(s) studied
Management of patients with recurrent aphthous ulcers

Interventions
Treating recurrent aphthous ulcers on 64 patients (divided into 4 groups) with three laser wavelength (808nm,660nm,635nm) controlled with placebo as application of an inactivated laser as follows:

1. GaAs 635 nm gallium arsenide laser:
Power: 220 milliwatts
Fluency: 4.2 J/cm³
Depth of tissue: 1 cm
The necessary irradiation time(treatment time): 19 seconds / 2 times, separated by 30 seconds rest
Laser beam spot size: 0.5 cm²
Irradiance: 0.34 W/cm2
Application method: direct contact . (to focus the rays over the ulcer area)

2. AlGaInP 660 nm Aluminum gallium indium phosphide laser:
Power: 150 milliwatts
Fluency: 4.1 J/cm³
Depth of tissue: 1 cm
Irradiation time: Treatment Time: 27 seconds/twice, with 30 seconds rest between them
Laser beam spot size: 0.5 cm²
Irradiance: 0.24 W/cm²
Application method: direct contact.

3. GaAlAs 808 nm gallium aluminum arsenide laser:
Power: 250 milliwatts

Fluency: 4 J/cm³
Depth of tissue: 1 cm
Irradiation time: Treatment Time: 16 seconds/twice, with 30 seconds rest between them
Laser beam spot size: 0.5 cm²
Irradiance: 0.40 W/cm²
Application method: direct contact.

The samples were sorted randomly, where 4 similar classifiers containing 4 symbols (English letters A, B, C, D) were placed, where each group had a previously defined symbol, and the classifiers were randomly drawn so that the first sixteen patients were entered in the group that was drawn first and The second sixteen patients in the group that were withdrawn secondly, and so on... with the help of an assistant researcher.

Follow up for 7 days.

Intervention Type
Device

Pharmaceutical study type(s)
Dose response

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Klas-DX Intelligen LLLT Dose Unit

Primary outcome measure
1. Pain is measured using a visual analogue scale (VAS) at baseline, before treatment, directly after treatment, and on days 2, 3, 5, 7 after treatment.
2. Lesion size is measured using dental probe at baseline, before starting the treatment, and on days 3, 7.
3. Erythema is measured using a scale based on Greer et al rules on a 4-point scale at baseline before starting treatment and immediately after treatment, and on days 3, 7.
4. Patient Satisfaction Index is measured using VAS scale after ulcer healing.

Secondary outcome measures
Recurrence is measured after one month in same place of treatment.

Overall study start date
11/06/2019

Completion date
13/12/2022

Eligibility

Key inclusion criteria
1. Patients with one or more aphthous lesion.
2. The lesion site on the buccal or labial oral mucosa, tongue, or floor of the mouth.

3. The patient has a history of recurrence.
4. No more than 48 hours have passed since the appearance of the lesion until the working day.
5. The diameter of the ulcer does not exceed 5 mm.
6. Age of 20 to 40 years.
7. The patient can attend the follow-up.
8. no other treatments for the present apthous ulcers.
9. Avoid pungent foods and acidic drinks during the follow-up period.

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
64

Total final enrolment
64

Key exclusion criteria
1. Smokers
2. Patients with systemic conditions related to oral ulcers such as Crohn's disease
3. Patients taking antibiotics or anti-inflammatory drugs during the month before treatment

Date of first enrolment
06/10/2019

Date of final enrolment
20/09/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Clinical of the Oral Medicine Department
Mazzah High Way

Damascus
Syria
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Sponsor information

Organisation
Damascus University

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University/education

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ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location

Syria

Results and Publications

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

Intention to publish date
01/10/2023

Individual participant data (IPD) sharing plan
The datasets during the current study will be published as a supplement to the results publication

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			07/07/2023	No	Yes
Protocol file			07/07/2023	No	No