

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

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| <b>Submission date</b><br>30/06/2023   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>07/07/2023 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>10/07/2023       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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

### Contact name

Dr Esra'a AlHerafi

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## Additional identifiers

### Protocol serial number

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](mailto:info@damascusuniversity.edu.sy)), ref: 3331

### Study design

interventional single-center randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment, Efficacy

## 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/cm<sup>3</sup>

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 cm<sup>2</sup>

Irradiance: 0.34 W/cm<sup>2</sup>

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/cm<sup>3</sup>

Depth of tissue: 1 cm

Irradiation time: Treatment Time: 27 seconds/twice, with 30 seconds rest between them

Laser beam spot size: 0.5 cm<sup>2</sup>

Irradiance: 0.24 W/cm<sup>2</sup>

Application method: direct contact.

### 3. GaAlAs 808 nm gallium aluminum arsenide laser:

Power: 250 milliwatts

Fluency: 4 J/cm<sup>3</sup>

Depth of tissue: 1 cm

Irradiation time: Treatment Time: 16 seconds/twice, with 30 seconds rest between them

Laser beam spot size: 0.5 cm<sup>2</sup>

Irradiance: 0.40 W/cm<sup>2</sup>

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

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Klas-DX Intelligen LLLT Dose Unit

**Primary outcome(s)**

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.

**Key secondary outcome(s)**

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

**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 aphthous ulcers.
9. Avoid pungent foods and acidic drinks during the follow-up period.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

20 years

**Upper age limit**

40 years

**Sex**

All

**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

**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

**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? |
|---|---------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> |         |              | 07/07/2023 | No             | Yes             |
| <a href="#">Protocol file</a>                 |         |              | 07/07/2023 | No             | No              |