

# Evaluation of the effect of a low-level laser in the surgical treatment of periodontal pockets

<b>Submission date</b> 22/06/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/07/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/07/2021	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Background and study aims

Periodontal pockets are spaces surrounding the teeth under the gum line and are a symptom of periodontitis (gum disease). This study aims to evaluate the effect of a low-level laser in the surgical treatment of periodontal pockets.

Who can participate?

Healthy non-smoking adults between 35-50 years old with periodontal pockets

What does the study involve?

Participants' periodontal pockets are treated with either surgery (open flap debridement) or surgery and a low-level laser for 3 days (first, third and seventh days). Periodontal pockets, pain and dental hypersensitivity are measured before and after surgery

What are the possible benefits and risks of participating?

Both treatments are safe and should not cause any additional risks.

Where is the study run from?

Damascus University (Syria)

When is the study starting and how long is it expected to run for?

August 2020 to December 2021

Who is funding the study?

Damascus University (Syria)

Who is the main contact?

Dr Ghena Alshakoush  
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## Contact information

Type(s)

Scientific

**Contact name**

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

Nil known

## **Study information**

**Scientific Title**

Evaluation of the effect of biostimulation of the low-level laser in addition to surgical treatment of periodontal pockets - open flap debridement: a clinical comparative study

**Acronym**

LLL

**Study objectives**

Treating periodontal pockets with open flap debridement in addition to a low-level laser (LLL) is more effective than not using it.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 16/09/2020, Damascus University Ethics Committee (Dental College, Damascus University, Mazzeh Highway, Damascus, Syria; +963 (0)1133923486; sr.srd@damasuniv.edu.sy), ref: not applicable

**Study design**

Single-center interventional blinded comparative study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Periodontal pockets

**Interventions**

This is a split-mouth study. In the control group periodontal pockets are treated with open flap debridement (OFD). In the study group in addition to OFD periodontal pockets are treated with a low-level laser (808 nm) for 3 days (first, third and seventh days).

**Intervention Type**

Device

**Phase**

Phase I

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

Low level laser

**Primary outcome(s)**

1. Periodontal pockets measured by UNC15 probe at baseline and after 1 month of the surgery
2. Pain measured using a visual analogue scale after 24 hours and 3 and 7 days
3. Dental hypersensitivity measured using air syringe after 7 days and 1 and 3 months after surgery

**Key secondary outcome(s)**

1. Relative Attachment Level (RAL) measured using a periodontal probe at baseline and after 1 month
2. Severity of gingivitis measured using Gingival Index (GI) at baseline and after 1 month

**Completion date**

30/12/2021

**Eligibility****Key inclusion criteria**

1. Age between 35-50 years old
2. Periodontal depth from 7 mm and more after scaling and root planing stage

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Patients with diabetes
2. Smokers
3. Pregnant women
4. Patients who have been taking antibiotics for more than 3 months before the surgery
5. Patients who have had surgery in less than 6 months from the beginning of the treatment

**Date of first enrolment**

01/10/2020

**Date of final enrolment**

20/12/2021

**Locations**

**Countries of recruitment**

Syria

**Study participating centre**

**Damascus University**

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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

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ghena Alshakoush (ghinash84@gmail.com).

**IPD sharing plan summary**

Available on request