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

Submission date 22/06/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/07/2021	**Overall study status** Completed	
Last Edited 26/07/2021	**Condition category** Oral Health	

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 debridment) 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
ghinash84@gmail.com

Contact information

Type(s)

Scientific

Contact name
Dr Ghena Alshakoush

ORCID ID
https://orcid.org/0000-0002-6314-0807

Contact details
Baramkeh
Amin Alrihany St.
Jasmine Building
Damascus
Syria
-
+963 (0)956999341
ghinash84@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Periodontal pockets

Interventions
This is a split-mouth study. In the control group periodontal pockets are treated with open flap debridment (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 measure
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

Secondary outcome measures
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

Overall study start date
01/08/2020

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

Age group
Adult

Sex
Both

Target number of participants
10 patients (70 teeth)

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
-

Damascus
Syria
-

Sponsor information

Organisation
Damascus University

Sponsor details
Al-Mazzeh Highway
Damascus
Syria
-
+963 (0)2142581
info@damascusuniversity.edu.sy

Sponsor type
University/education

Website
http://damasuniv.edu.sy/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Results and Publications

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

Intention to publish date
30/12/2022

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