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The use of lasers in the treatment of gum disease

Submission date	Recruitment status	[_] Prospectively registered
25/03/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/03/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/04/2021	Oral Health	

Plain English summary of protocol

Background and study aims

Gum disease is a very common condition where the gums become swollen, sore or infected. Typical treatment for periodontal disease is scaling and root planing (SRP). This is a nonsurgical method that includes cleaning the surfaces of teeth and their roots, which may be exposed due to gum recession.

Laser treatment is a tissue-preserving, regenerative, and bone-building procedure. In general dentistry, the dentist uses a laser to access an infected pocket to kill the infected tissue and bacteria. Once the infected tissue is removed and the root is exposed, the calculus is removed with an ultrasonic root cleaner instead of scraping with hand tools. Lastly, laser energy is used to warm the stem cell that contains blood in the pocket, which creates a seal of tissues against the tooth root. Laser treatment ensures that no tissue is subtracted or gum tissue is reduced to a lower level on purpose. It also stimulates stem cells in the tissues to form new connective tissues, bone, and collagen. The body's healing process then regenerates the lost ligaments and bone around the tooth.

The aim of the study was the combined application of Er:YAG and Nd:YAG laser irradiation to improve periodontal probing depths.

Who can participate?

Patients with severe periodontal (gum) disease.

What does the study involve?

The study involves a baseline examination, a laser treatment session and a reassessment after two months.

What are the possible benefits and risks of participating?

A possible benefit might be an improved periodontal condition. With the applied laser settings no side effects are expected.

Where is the study run from?

Medical University of Vienna (Austria)

When is the study starting and how long is it expected to run for?
January 2018 to January 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Markus Laky
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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
MUW-LP-15

Study information

Scientific Title
Neodymium-doped yttrium aluminum garnet (Nd:YAG) laser and erbium-doped yttrium aluminum garnet (Er:YAG) laser in the treatment of periodontal disease

Study objectives

Er:YAG and Nd:YAG laser application as an adjunct to conventional periodontal treatment might result in healthier periodontal conditions

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/11/2017, Ethics committee of the Medical University of Vienna (Borschkegasse 8b /6, 1090 Vienna, Austria; +43 1 40400 21470; ethik-kom@meduniwien.ac.at), ref: 1747/2017

Study design
Single-blind randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Periodontal disease

Interventions
The periodontal patients in the test group had a laser intervention. Laser setting for the Nd:YAG laser was 2.5 W with an initiated fiber without water-cooling. Then a 60 seconds irradiation of the Er:YAG laser LightWalker was applied. The laser settings were 40 mJ, 40 Hz. Finally, 30 seconds stabilization of the forming blood clot was accomplished with a Nd:YAG laser 3.5 W.

In the control group all the steps were performed without activating the laser device.

Re-assessment was done eight weeks post-treatment.

A 1:1 randomization was performed. Before the start of the trial a 1:1 randomization list was prepared by flipping of a coin. After inclusion of the patient the allocation of the patient according to the randomization list was revealed to the treating clinican.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Er:YAG and Nd:YAG laser

Primary outcome measure
Periodontal probing depth (mm) measured using dental probe at baseline and two months after the intervention

Secondary outcome measures
Clinical attachment level measured using a periodontal probe (periodontal probing depth + clinical recession) at baseline and two months after the intervention
Bleeding on probing measured using dental probe at baseline and two months after the intervention

Overall study start date
26/01/2015

Completion date
21/01/2019

Eligibility

Key inclusion criteria
Adults with least one site with a probing depth of ≥ 6 mm around eight weeks post-completion of initial supra- and subgingival periodontal debridement

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
22

Total final enrolment
22

Key exclusion criteria
Systemic diseases which could potentially influence outcome of the therapy (e.g. diabetes mellitus, pregnancy, immunosuppression, malignant diseases)

Date of first enrolment
08/01/2018

Date of final enrolment
08/01/2019

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Vienna
Spitalgasse 23
Vienna
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1090

Sponsor information

Organisation
Medical University of Vienna

Sponsor details
University Clinic of Dentistry
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Sponsor type
University/education

Website
http://www.meduniwien.ac.at/homepage/1/homepage/

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

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

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article			06/04/2021	Yes	No