

Treatment of periodontal disease with additional low-level laser therapy

Submission date 25/08/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/04/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Chronic periodontitis is a disease which attacks the tissues surrounding the teeth and affects almost every second adult. As the disease proceeds, the bones and teeth can be damaged, which can lead to tooth loss. Any periodontal pockets that have formed require deep cleaning which can be combined with other treatment options in able to improve the therapy outcome. The aim of this study is to investigate a low-level laser as a complementary treatment to conventional periodontal treatment.

Who can participate?

Adults aged 25-55 with periodontal disease

What does the study involve?

All participants will receive the same treatment - standard periodontal treatment (deep cleaning) on both sides of the mouth. Each participant will have one side of their mouth randomly allocated to receive laser therapy.

What are the possible benefits and risks of participating?

The possible benefit of participating is that the laser may improve the success of regular gum treatment.

Where is the study run from?

University Clinic of Dentistry, Medical University of Vienna (Austria)

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

October 2016 to July 2023

Who is funding the study?

Medical University of Vienna (Austria)

Who is the main contact?

1. Prof. Rausch-Fan, xiaohui.rausch-fan@meduniwien.ac.at
2. Dr Selma Dervisbegovic, selma.dervisbegovic@meduniwien.ac.at

Contact information

Type(s)

Scientific

Contact name

Dr Selma Dervisbegovic

ORCID ID

<https://orcid.org/0000-0003-3325-013X>

Contact details

Sensengasse 2A

Vienna

Austria

1090

+43 (0)1400704720

selma.dervisbegovic@meduniwien.ac.at

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Adjunctive lowlevel laser therapy in periodontal treatment – a randomized clinical split-mouth trial

Acronym

LLLT

Study objectives

Adjunctive therapy with lowlevel laser therapy (LLLT) results in better clinical parameters, compared to debridement only.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 14/06/2017, Ethics Committee Medical University of Vienna (Ethikkommission Medizinische Universität Wien) (Borschkegasse 8b/E06, Vienna, 1090, Austria; +43 (0)1 40400 21470; ethik-kom@meduniwien.ac.at), ref: EK Nr.: 2241/2016

Study design

Single-centre interventional double-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Dental clinic

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Moderate to severe periodontitis

Interventions

Participants were randomised into a split-mouth design, with the allocation of the side to be treated (left or right) performed by drawing lots before the initial periodontal examination.

Clinical and microbiological parameters were obtained in the initial examination. All of the sites received non-surgical therapy. Subsequently, one side of each study participant's upper and lower jaws was treated with LLLT. The contralateral side remained untreated and served as a control. LLLT was carried out at sites with pockets in non contact mode and protective eyewear was provided to all participants. Clinical and microbiological parameters were repeated 12 weeks after initial treatment.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Denlase Diode Laser

Primary outcome measure

Bleeding on probing, assessed during probing with a calibrated standard probe at baseline and 12 weeks after the last treatment (re-evaluation)

Secondary outcome measures

1. Oral hygiene, assessed using the Approximal-Plaque-Index (API) and the Papillary Bleeding Index (PBI) at the initial examination (baseline) and 12 weeks after the last treatment (re-evaluation)
2. Clinical attachment level, measured to the nearest millimeter using a calibrated standard probe at baseline and re-evaluation
3. Periodontal pocket depth, measured to the nearest millimeter using a calibrated standard probe at baseline and re-evaluation

Overall study start date

01/10/2016

Completion date

01/07/2023

Eligibility

Key inclusion criteria

1. Moderate to severe periodontitis with a Periodontal Screening Index of 3 or 4; in regards to new classification: localized or generalized periodontitis of periodontal stage II, III or IV with grades B or C
2. Age 25-55 years
3. Presence of at least one site in each quadrant with probing depths above ≥ 5 mm with bleeding on probing
4. Radiologically-detectable alveolar bone loss in all quadrants
5. Good general health

Participant type(s)

Patient

Age group

Adult

Lower age limit

25 Years

Upper age limit

55 Years

Sex

Both

Target number of participants

20

Total final enrolment

20

Key exclusion criteria

1. Pregnancy
2. Intake of antibiotics in the last 6 months
3. Periodontal treatment during the last 6 months
4. Infectious disease, chronic pulmonary disease, immunosuppressive medication or immunodeficiency, cancer, diabetes, other apparent oral infection

Date of first enrolment

01/07/2017

Date of final enrolment

20/08/2022

Locations

Countries of recruitment

Austria

Study participating centre

University Clinic of Dentistry, Medical University of Vienna

Sensengasse 2A

Vienna

Austria

1090

Sponsor information

Organisation

Medical University of Vienna

Sponsor details

Spitalgasse 23

Vienna

Austria

1090

+43 (0)1 40160-0

office-unizahnklinik@meduniwien.ac.at

Sponsor type

University/education

Website

<http://www.meduniwien.ac.at/homepage/1/homepage/>

ROR

Funder(s)

Funder type

Government

Funder Name

Medizinische Universität Wien

Alternative Name(s)

Medical University of Vienna, MediUni Wien

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Austria

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/01/2024

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made 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		25/04/2025	28/04/2025	Yes	No