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Treatment of periodontal disease with additional low-level laser therapy

Submission date
25/08/2023

Recruitment status
No longer recruiting

Registration date
16/10/2023

Overall study status
Completed

Last Edited
28/04/2025

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
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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
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 (Ethikommission 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
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+43 (0)1 40160-0
office-unizahnklinik@meduniwien.ac.at

Sponsor type
University/education

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

ROR

https://ror.org/05n3x4p02

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