ISRCTN15434154 https://doi.org/10.1186/ISRCTN15434154

Treatment of Periodontitis with a Photoactivated Disinfection System

Submission date	Recruitment status	[ ] Prospectively registered
24/07/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/08/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/08/2018	Digestive System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic periodontitis is a disease which attacks the tissues surrounding the teeth and has a very high prevalence in adults. As periodontitis progresses, the bones and teeth can be damaged, which can lead to tooth loss if left untreated. Any periodontal pockets that have formed require deep cleaning called scaling and root planing in order to enable healing. In some severe cases, the deep cleaning is combined with other treatment options in able to improve the therapy outcome. Photoactivated disinfection is a treatment method that is associated with the use of a light source and a photosensitizer to disinfect the area and clear bacteria. The aim of this study is to investigate photoactivated disinfection as a complementary treatment to conventional periodontal treatment such as deep cleaning.

Who can participate?
Adults aged over 35 with periodontitis

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 photoactivated disinfection.

What are the possible benefits and risks of participating?
The possible benefit of participating is that photoactivated disinfection may improve the success of regular gum treatment. The possible risk is that the dye used in the treatment may result in transient staining of the oral mucosa.

Where is the study run from?
University Clinical of Dentistry, Medical University of Vienna, Austria

When is the study starting and how long is it expected to run for?
October 2014 to June 2016

Who is funding the study?
Medical University of Vienna (Austria)

Who is the main contact?
1. Professor Rausch-Fan, xiaohui.rausch-fan@meduniwien.ac.at
2. Dr Selma Husejnagic, selma.husejnagic@meduniwien.ac.at

Contact information

Type(s)
Scientific

Contact name
Dr Selma Husejnagic

ORCID ID
https://orcid.org/0000-0001-8727-8205

Contact details
Sensengasse 2 A
Vienna
Austria
1090

Additional identifiers

Protocol serial number
EK Nr: 1860/2014

Study information

Scientific Title
Photoactivated Disinfection with a Light-Emitting Diode in Periodontal Treatment – a Randomized Controlled Clinical Split-mouth Trial

Acronym
PADLED

Study objectives
Adjunctive Photoactivated Disinfection with a red LED has an additional beneficial effect in treatment of chronic periodontitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethikommission Medizinische Universität Wien, 13/02/2015, 1860/2014

Study design
Interventional single-centre randomised split-mouth randomised controlled trial

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic periodontitis

Interventions
Participants were randomised into a split-mouth design, with allocation of the side to be treated (left or right) performed by drawing lots before the initial periodontal examination.
Clinical and microbiological parameters were evaluated in the initial examination. Subsequently, supra and subgingival debridement was performed using ultrasonic instruments, universal curettes and Gracey curettes. One side of each study participant's upper and lower jaws was treated with photoactivated disinfection during the two final cleaning sessions. The contralateral side remained untreated and served as a control. Adjuvant treatment was carried out at six locations around all teeth (mesiobuccal, buccal, distobuccal, mesiolingual, lingual and distolingual), and protective eyewear was provided to all participants. The photosensitizer, a 0.01% tolonium chloride solution, was applied to the pocket and after 60 seconds the area was irradiated with light for 60 seconds per location according to the manufacturer. The pockets were than irrigated with physiological saline solution. Clinical and microbiological parameters were repeated 12 weeks after initial treatment.

Intervention Type
Device

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

Key secondary outcome(s))
1. Oral hygiene, assessed using The Approximal-Plaque-Index (API) and the Papillary Bleeding Index (PBI) at the initial examination (baseline), at debridement 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

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Presence of moderate to severe periodontitis
2. Aged 35 years or older
3. Probing depths > 5 mm in at least one site in each quadrant
4. Radiologically detectable alveolar bone loss in all quadrants
5. Good general health

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
1. Pregnant
2. Systemic or local antimicrobial treatment in the preceding 6 months
3. Periodontal treatment in the preceding 6 months
4. The presence of an infectious disease, chronic pulmonary disease, cancer or diabetes and other apparent oral infections
5. Intake of immunosuppressive medication or immunodeficiency

Date of first enrolment
14/02/2015

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Vienna
Spitalgasse 23
Vienna
Austria
1090

Sponsor information

Organisation
Medical University of Vienna

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
Not defined

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

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