







Evaluation of antimicrobial photodynamic therapy and doxycycline during supportive periodontal therapy

Submission date 22/02/2021	Recruitment status No longer recruiting	 Retrospectively registered
		 Protocol added
Registration date 24/02/2021	Overall study status Completed	 SAP not yet added
		 Results added
Last Edited 30/03/2023	Condition category Oral Health	 Raw data not yet added
		 Study completed

Plain English Summary

Background and study aims

Severe forms of periodontal (gum) disease require additional systemic antibiotics as well as the usual non-surgical periodontal therapy (subgingival instrumentation). However, in light of the worldwide increasing problem of microbial resistance towards antibiotics, it is important to find alternatives to systemic antibiotics. Locally administered doxycycline or photodynamic therapy has been already investigated in the treatment of periodontal diseases, but no direct comparison has been performed until now. Thus, the aim of this study is to evaluate the effectiveness of locally administered doxycycline or photodynamic therapy in persistent periodontal pockets in periodontal patients.

Who can participate?

Patients aged over 18 who had been previously treated for periodontitis with persistent sites of inflammation

What does the study involve?

The study involves periodontal non-surgical treatment with conventional methods (ultrasonics). All patients will be divided into three treatment groups: one group receives after mechanical treatment two sessions of photodynamic therapy at persistent inflamed periodontal pockets, the second group will receive in the inflamed pockets a paste containing doxycycline, while the third group will not receive any additional treatment. The researchers evaluate the effectiveness of the treatment by measuring clinical parameters (probing depth, attachment level, bleeding on probing) and determining the quantity of certain periodontal pathogens as well as inflammatory markers. All these will be determined before and 3, 6 and 12 months after therapy.

What are the possible benefits and risks of participating?

The benefits are optimal periodontal treatment performed by a periodontal specialist, as well as obtaining additional microbiological and immunological data related to effectiveness of the treatment. There are no expected side-effects since this is the least invasive periodontal treatment.

Where is the study run from?
University Iuliu-Hatieganu Cluj-Napoca (Romania)

When is the study starting and how long is it expected to run for?
March 2015 to October 2020

Who is funding the study?
1. Investigator initiated and funded
2. Brendent Dental GmbH (Germany)

Who is the main contact?
Dr Raluca Cosgarea
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Protocol/serial number
#390/02.07.2015

Study information

Scientific Title

Clinical and microbiological evaluation of local doxycycline and antimicrobial photodynamic therapy during supportive periodontal therapy: a randomized clinical trial

Acronym

HelLig

Study hypothesis

Photodynamic therapy (PDT) or antibiotic local-drug-delivery (LDD) provide similar clinical results in persistent/recurrent periodontal pockets of periodontal patients enrolled in supportive periodontal therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 02/07/2015, ethical committee of the Faculty of Medicine and Pharmacy, University Iuliu Hatieganu Cluj-Napoca (Comisia de etica UMF Iuliu Hatieganu Cluj-Napoca, Str. Victor Babes nr 8, Cluj-Napoca, Romania; +40 (0)264 597256; etica.cercetare@umfcluj.ro), ref: #390/02.07.2015

Study design

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

See additional file ISRCTN17209965_PIS (added 01/03/2021)

Condition

Persistent/recurrent periodontal pockets of patients with periodontal disease

Interventions

Periodontitis patients enrolled in supportive periodontal therapy are randomly treated as follows:

Group A (n=35): subgingival instrumentation (SI) + photodynamic therapy (PDT) and 7 days later 2nd PDT

Group B (n=35): SI + locally delivered doxycycline) LDD

Group C (n=35): SI (control)

Prior to intervention and at 3, 6 and 12 months after therapy, probing pocket depths, clinical attachment level, number of treated sites with bleeding on probing (nBOP), full-mouth-plaque

and bleeding-scores (gingival-bleeding-index, %BOP) will be recorded and analyzed. At the same time points, eight periodontopathogens and immunomarkers will quantitatively determined.

Intervention Type

Mixed

Primary outcome measure

Number of bleeding sites measured with a mm-scaled periodontal probe and noted on patient files at baseline prior to therapy and at 3, 6 and 12 months

Secondary outcome measures

Measured at baseline prior to therapy and at 3, 6 and 12 months:

1. Probing pocket depth measured with a mm-scaled periodontal probe and noted on patient files
2. Clinical attachment level measured with a mm-scaled periodontal probe and noted on patient files
3. Bleeding indexes measured with a mm-scaled periodontal probe and noted on patient files
4. Plaque indexes assessed dichotomously on patient data sheets after plaque coloration with a disclosing dye
5. Periodontal pathogens measured using real-time PCR
6. Immunomarkers from the sulcus measured using ELISA test

Overall study start date

10/03/2015

Overall study end date

01/10/2020

Eligibility

Participant inclusion criteria

1. Minimum age 25 years
2. Patients should be enrolled in a regular maintenance program (after completion of active periodontal therapy)
3. Diagnoses of chronic periodontitis
4. Minimum one site per quadrant with PD \geq 4 mm and BOP+
5. Good level of oral hygiene [plaque control record (PCR) after O'Leary 1972 \leq 30%]
6. Systemically healthy: no history of diseases that may influence the severity or progression of the periodontal disease (Down syndrome, HIV, diabetes mellitus type 1 and 2), post-irradiation in the head and neck area, infectious diseases or heart diseases that need a prophylactic antibiotics before dental treatments, liver diseases
7. Informed written consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

105

Total final enrolment

105

Participant exclusion criteria

1. Systemic or local use of antibiotics within the preceding 3 months
2. Medication that may interact with doxycycline (e.g., coumarin derivatives, containing alcohol derivatives, 5-fluorouracil/ disulfiram derivatives, amprenavir oral solutions, lopinavir/ritonavir oral solution)
3. Medication that may influence the periodontium: cyclosporin A, compounds of phenytoin, calcium channel blockers (nifedipine, verapamil, amlodipine, diltiazem)
4. Pregnancy or lactation
5. Patients who don't match the inclusion criteria

Recruitment start date

01/10/2015

Recruitment end date

01/10/2017

Locations

Countries of recruitment

Romania

Study participating centre

University Iuliu-Hațieganu Cluj-Napoca

Policlinic of prosthodontics

Str. Clinicilor nr 32

Cluj-Napoca

Romania

400506

Sponsor information

Organisation

Iuliu Hațieganu University of Medicine and Pharmacy

Sponsor details

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Sponsor type

University/education

Website

<http://www.umfcluj.ro/en/>

ROR

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Organisation

University of Bern

Sponsor details

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Sponsor type

University/education

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Funder(s)

Funder type

Industry

Funder Name

Investigator initiated and funded

Funder Name

Brendent Dental GmbH

Results and Publications

Publication and dissemination plan

1. Two publications
2. Oral presentation at dental congresses

Intention to publish date

01/10/2021

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 Raluca Cosgarea (ralucacosgarea@gmail.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			01/03/2021	No	Yes
Protocol file			01/03/2021	No	No
Results article	3 and 6 months results	09/03/2021	28/10/2021	Yes	No
Results article	12 months results	30/05/2022	30/03/2023	Yes	No