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Evaluation of antimicrobial photodynamic therapy and doxycycline during supportive periodontal therapy

Submission date
22/02/2021

Recruitment status
No longer recruiting

Registration date
24/02/2021

Overall study status
Completed

Last Edited
30/03/2023

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

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 wolrdwide 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

Clinical Trials Information System (CTIS)
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 objectives
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

Completion date
01/10/2020

Eligibility

Key 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 ≥4 mm and BOP+
5. Good level of oral hygiene [plaque control record (PCR) after O'Leary 1972 ≤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 antibiosis before dental treatments, liver diseases
7. Informed written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
105

Key exclusion criteria
1. Systemic or local use of antibiotics within the preceding 3 months
2. Medication that may interact with doxycyclin (e.g., coumarin derivates, containing alcohol derivates, 5-fluorouracil/ disulfiram derivates, 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

Date of first enrolment
01/10/2015

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
Romania

Study participating centre
University Iuliu-Hatieganu Cluj-Napoca
Policlinic of prosthodontics
Str. Clinicilor nr 32
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Sponsor information

Organisation
Iuliu Haţieganu University of Medicine and Pharmacy

ROR
https://ror.org/051h0cw83

Organisation
University of Bern

Funder(s)

Funder type
Industry

Funder Name
Investigator initiated and funded

Funder Name
Brendent Dental GmbH

Results and Publications

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?
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
Participant information sheet			01/03/2021	No	Yes
Protocol file			01/03/2021	No	No