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Non-surgical treatment of inflammation of the soft tissues around a dental implant

Submission date
02/12/2023

Recruitment status
No longer recruiting

Registration date
05/12/2023

Overall study status
Completed

Last Edited
05/12/2023

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Peri-implant mucositis (PiM) is a condition that frequently occurs around dental implants characterized by an inflammation of the tissues around the dental implants caused by dental plaque, which without treatment can destroy the bone that supports the dental implants. Peri-implant mucositis occurs in about half of the population with dental implants that, if left untreated, leads to peri-implantitis. Because it is a reversible condition when inflammation is properly managed, its treatment is considered the most effective measure to prevent dental implant loss.
The first step of treatment (removal of irritants) is called mechanical debridement. Antibiotic gels may be additionally applied after the procedure because evidence indicates that local delivery of antimicrobials in peri-implant mucositis along with mechanical debridement provides an extra benefit compared to mechanical debridement alone and aids with the control of the growth of pathogenic bacteria. Local drug delivery (LDD) systems provide a higher concentration of the antimicrobial with a sustained release over a longer duration of time.
Topically applied antibiotic gels can help control bacterial infection. Topical antibiotic gels can be applied in the space between the dental implant and gums after mechanical debridement. However, oral antibiotics may be necessary to eliminate infection-causing bacteria.
The aim of this study is to evaluate the effect of a new piperacillin and tazobactam gel, in comparison with a placebo (dummy) gel, in the treatment of peri-implant mucositis after mechanical debridement. Treatment will be performed by a periodontist. Peri-implant mucositis treatment aims to thoroughly clean the pockets around the implant and prevent damage to the surrounding bone.

Who can participate?
Men and women aged 18 years and over who are suffering from peri-implant mucositis

What does the study involve?
Participants will be randomly allocated to receive mechanical debridement of the implants of interest accompanied by either Gelcide® gel or placebo (inactive) gel. Follow-up will be at 3 and 6 months.

What are the possible benefits and risks of participating?
Participants may benefit from improved gum health and reduced inflammation. No risk is involved with the use of the antimicrobial product.

Where is the study run from?
Victor Babes University Timisoara (Romania)

When is the study starting and how long is it expected to run for?
January 2022 to September 2023

Who is funding the study?
MegaGen (Romania)

Who is the main contact?
Dr Ilyes Ioana, ioana.veja@umft.ro

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
57/2022

Study information

Scientific Title
A single dose of piperacillin plus tazobactam pellicular coating as an adjunct to professional mechanical plaque removal in patients with peri-implant mucositis: a 6-month double-blind randomized clinical trial

Acronym
PIM-ATB

Study objectives
The null hypothesis (H0) was that no statistically significant differences are observed with respect to the clinical parameters pocket probing depth (PPD), bleeding on probing (BoP), modified plaque index (mPlI) and modified bleeding index (mBI) between the two treatment modalities (i.e., adjunctive delivery of piperacillin plus tazobactam vs placebo).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/08/2022, Research Ethics Committee of the Victor Babeş University of Medicine and Pharmacy Timişoara (Piata Eftimie Murgu 2A, Timisoara, 300041, Romania; +40 (0)256 466001; cecs@umft.ro), ref: 57/2022

Primary study design
Interventional

Study design
Prospective double-blinded randomized placebo-controlled clinical trial with a parallel design of 6-month duration

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peri-implant mucositis

Interventions
The study includes a cohort of 40 patients equally divided into one of the two groups – A and B. Participants will be selected from patients of the Department of Periodontology of the Victor Babes University of Medicine and Pharmacy Timisoara, Romania.

Baseline: Prior to PiM treatment, full-mouth supragingival scaling was performed in all subjects. Each patient was assigned to one of the two treatment groups according to computer-generated randomization. One implant with PiM in each patient was selected for the study. Mechanical debridement of the implants of interest was performed using an ultrasonic scaler with a plastic tip (PIEZON® MASTER 700 with PIEZON® PI instrument, EMS, Nyon, Switzerland), and air polishing (PERIOFLOW® handpiece, AIRFLOW® PLUS powder, EMS, Nyon, Switzerland) at all sites. Instrumentation was followed by subgingival gel application, depending on the patient's group: Group A [Gelcide® (test)]: topical application of Gelcide® (Italmed, Firenze, Italy); Group B [Placebo (control)]: topical application of a placebo gel, similar in aspect and consistency with the test gel.

Post-application instructions for groups A and B were as follows: gentle brushing of the application area performed twice a day, removal of interdental plaque once a day, rinsing with 0.20% chlorhexidine solution (Dentaton®, Ghimas s.p.a., Casalecchio di Reno, Italy) twice a day for 2 weeks following treatment. All participants received standardized oral hygiene instructions with the use of an electric toothbrush and individualized interdental brushes or dental floss.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Implant pocket probing depth (PPD) measured from the mucosal margin to the bottom of the probable pocket and evaluated at six sites per implant (i.e., disto-buccal, mid-buccal, mesio-buccal, mesio-lingual/palatal, mid-lingual/palatal, disto-lingual/palatal) at the clinical baseline evaluation (before therapy) and the 3 and 6-month re-evaluations

Key secondary outcome(s)
Measured at baseline, 3 and 6 months:
1. Full mouth bleeding score (FMBS) recorded at six sites per tooth: mesiobuccal, midbuccal, distobuccal, disto-oral, midoral, and mesio-oral
2. Mean full mouth plaque score (FMPS) evaluated at six sites per tooth at 30 seconds from the survey
3. Overall bleeding index (BOP) evaluated at six sites per tooth/implant at 30 seconds from the survey
4. Number of the following five keystone bacterial pathogens measured using molecular genetic analysis, micro–IDent A Test at baseline and 3 months:
4.1. Aggregatibacter actinomycetemcomitans
4.2. Porphyromonas gingivalis
4.3. Prevotella intermedia
4.4. Tannerella forsythia
4.5. Treponema denticola

Completion date
01/09/2023

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Absence of relevant medical conditions
3. Partially edentulous subjects with healthy or treated periodontal conditions enrolled in a regular supportive care program
4. Peri-implant mucositis defined as ≥1 implant site with the presence of BoP and absence of radiographic bone loss compared with a previous radiograph (Renvert, et al., 2018)
5. Implant in function for ≥1 year
6. Full-Mouth Plaque Score (FMPS) ≤25
7. Full-Mouth Bleeding Score (FMBS) ≤25

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Uncontrolled medical conditions
2. Pregnant or lactating females
3. Tobacco smoking ≥10 cigarettes/day
4. Untreated periodontal conditions
5. Removable implant -retained prosthesis or other chronic systemic medications that could interfere with the study outcomes
6. Use of antibiotics in the past 3 months
7. Subjects treated for ≥2 weeks with any medication known to affect soft tissue conditions (e.g. phenytoin, calcium antagonists, cyclosporin, blood thinners and nonsteroidal anti-inflammatory drugs) within 1 month of the baseline examination
8. Failure to sign written informed consent

Date of first enrolment
01/09/2022

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
Romania

Study participating centre
Victor Babes University of Medicine and Pharmacy Timisoara
Anton Sculean Center for Research of Periodontal and Periimplant Diseases
Department of Periodontology
Bulevardul Revoluției 1989, no. 9
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Sponsor information

Organisation

MegaGen Dental Implant Romania

Funder(s)

Funder type
Industry

Funder Name
MegaGen Dental Implant Romania

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the study will be stored in a non-publically available repository: archives of the Department of Periodontology of the Victor Babes University. When the data will become available and for how long: 5 years after the end of the study, indefinitely. Comments on data anonymisation: numbers were attributed to patient's names.

IPD sharing plan summary
Available on request