Surgical peri-implantitis treatment: regenerative approach and adjuvant antibiotic intervention

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Regenerative therapy provides similar or better clinical results as opposed to resective surgical therapy in 3- and 4-wall peri-implantitis bone defects; The use of adjuvant systemic antibiotics provides superior clinical, radiographical and...

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27505

Source
NTR

Brief title
OZPI

Health condition

Peri-implantitis

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

- Mean peri-implant bleeding on probing (BoP)

Secondary outcome

- Full-mouth BoP; - Mean peri-implant and full mouth suppuration on probing score (SoP); - Mean peri-implant probing and full-mouth pocket depth (PPD) - Mean radiographical bone height in millimetres - Marginal soft tissue recession (REC) - Radiographic marginal peri-implant bone level and bone defect configuration on standardized intraoral radiographs and cone-beam computed tomographies - Microbiological composition of the peri-implant and periodontal area; - Implant failure, defined as implant mobility of previously osseointegrated implants and removal of non-mobile implants because of progressive marginal bone loss or infection; - Tooth loss, defined as removal of teeth because of progressive marginal bone loss or infection; - failure of peri-implantitis treatment at 12 months after treatment: probing pocket depth (PPD) of ≥ 6mm in combination with bleeding on probing (BOP) or suppuration on probing (SOP) and progressive radiographical peri-implant bone loss - Complication and adverse events

Study description

Background summary

Rationale: Peri-implantitis is an infectious condition of the tissues surrounding dental endosseous implants resulting in clinical signs of inflammation (bleeding and/or suppuration on probing) and loss of supporting bone. Bone defects can occur around the implant as a result of the inflammation. Various treatment modalities have been described to treat the bone defects. Despite these various treatment strategies, the most effective treatment option remains unclear. Therefore the search for a potentially beneficial strategy to treat the peri-implant bone defects is indispensable. Resection of the excess gingiva has proven to be a predictable treatment modality to reinstate peri-implant health. However, regaining the lost bone as a means to reinforce the implant stability is preferred. One such potential treatment modality might be augmentation of the bone defect with autologous bone and bone substitutes. Modern day bone substitutes could benefit the regrowth of the supporting bone surrounding the implants. Furthermore, the use of antibiotics has proven to be an effective adjunctive therapy in treating periodontitis. The periodontal pockets show similarities in microbiota with the peri-implant pocket. However, there is limited clinical evidence towards the effectiveness of adjunctive antibiotic therapy in the resective surgical treatment of peri-implantitis. Thorough research as to which treatment modality proves to be preferable is yet to be conducted. The aim of this study is therefore to assess the difference between a resective and a regenerative approach and to study the effect of adjuvant antibiotics in peri-implant surgery. Objective: The primary objectives of this study are as follows: 1. To compare the effect of a resective and regenerative surgical treatment approach in 3- and 4- wall peri-implantitis bone defects; 2. To evaluate the effect of adjuvant antibiotic therapy in 0-, 1- and 2 wall bone defects treated with resective peri-implant surgery. Study design: The study is designed as a randomized controlled trial. Study population: Adult patients with at least one

endosseous implant in the oral cavity showing clinical and radiographical signs of peri-implantitis will be included in this study. Intervention (if applicable): During surgery, the configuration of the peri-implant bone defect will determine the surgical procedure: a group with 3- and 4-wall bone defects (divided into groups 1 and 2) and a group with 0-, 1- and 2-wall bone defects (divided into groups 3 and 4). In all groups, the implant surface is exposed and decontaminated with air-abrasive instruments and titanium curettes. Group 1 will undergo resective therapy. The lap is surgically trimmed, minimal bone corrections might be executed and the gingiva will be repositioned slightly apically. Group 2 will undergo regenerative therapy. The bone defect will be reconstructed using a mixture of autogenous bone and a bone substitute. A collagen membrane will be placed, covering the reconstructed area and the gingiva will be repositioned. Additionally, all patients in groups 1 and 2 will receive prophylactic antibiotic treatment (amoxicillin). Group 3 will undergo resective surgery without adjuvant antibiotics to support the treatment (following the same protocol as group 1). Group 4 will receive the same resective surgery but with adjuvant antimicrobial aftercare (amoxicillin/metronidazole). Furthermore, the follow up will consist of 2 weeks rinsing with 0,12% chlorhexidine + 0,05% cetylpyridinium chloride without alcohol twice daily for 30 seconds for all groups. Main study parameters/endpoints: The main study parameter is mean peri-implant bleeding on probing (BoP) Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In addition to the regular treatment protocol, patients will receive one extra appointment for research purposes only. The described parameters will be collected during the regular appointments.

Study objective

Regenerative therapy provides similar or better clinical results as opposed to resective surgical therapy in 3- and 4-wall peri-implantitis bone defects; The use of adjuvant systemic antibiotics provides superior clinical, radiographical and microbiological outcomes as opposed to resective surgical therapy without antibiotics in 0-, 1- and 2-wall peri-implantitis bone defects.

Study design

1. 1st appointment: screening, presenting information about the study and informed consent form 2. 2nd appointment (Tpre): informed consent, medical health questionnaire, clinical, microbiological and radiographical parameters, scheduling nonsurgical treatment 3. Pretreatment: nonsurgical treatment using air-abrasive instruments, executed by a dental hygiënist 4. Re-evaluation (T0): unsuccessful result after peri-implant nonsurgical treatment after 3 months, recollection previous parameters and scheduling surgery 5. Surgery 6. 2 weeks follow-up (Tpostop): suture removal, data collection (x-ray, digital imaging, questionnaire), oral hygiene instruction 7. 3 months follow-up (T3): data collection (clinical and radiographical parameters, digital imaging, questionnaire), oral hygiene reinforcement 8. 6 months follow-up (T6): data collection (clinical parameters), oral hygiene reinforcement 9. 9 months follow-up (T9): data collection (clinical parameters), oral hygiene reinforcement 10. 12 months follow-up (T12): data collection (clinical and radiographical parameters, digital imaging, questionnaire), oral hygiene reinforcement

Intervention

- 3- and 4-wall bone defects: the use of bone substitutes - 0-, 1- and 2-wall defects: the use of systemic amoxicillin and metronidazole

Contacts

Public
University Medical Center Groningen
Jarno Hakkers

0612905710
Scientific
University Medical Center Groningen
Jarno Hakkers

0612905710

Eligibility criteria

Inclusion criteria

- the patient is ≥18 years of age; - adult patients with at least one endosseous implant in the oral cavity with clinical and radiographical evidence of peri-implantitis. Peri-implantitis is defined as probing pocket depth (PPD) of ≥ 6mm in combination with bleeding on probing (BOP) or suppuration on probing (SOP) and radiographic bone loss of ≥3mm after placing the definitive suprastructure (Berglundh et al. 2018); - the implants have been in function for at least 2 years; - the patient is capable of understanding and giving informed consent.

Exclusion criteria

Exclusion criteria prior to pre-treatment: - medical and general contra-indications for the procedure; - a history of local radiotherapy to the head and neck region; - pregnancy and lactation; - uncontrolled diabetes mellitus (HbA1c <7% or <53 mmol/mol); - use of intravenous bisphosphonates; - known allergy to chlorhexidine, amoxicillin and/or metronidazole; - long-term use of anti-inflammatory drugs - patient is incapable of performing basic oral hygiene measures as a result of physical or mental disorders; - implants with bone loss exceeding 2/3 of implant length or implants with bone loss beyond the transverse openings in hollow implants; - previous surgical treatment of the peri-implantitis lesions; - chronic bronchitis or asthma. Additional exclusion criteria after pre-

treatment: - no peri-implantitis remaining: minor BoP (< 20%), PPD < 6mm, plaque < 20%; - active periodontal disease at the remaining dentition (PPD ≥ 6mm, BOP ≥ 20%) or insufficient oral hygiene (plaque ≥ 20%); - use of antibiotics during the last 3 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2020
Enrollment:	123
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	15-11-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49393
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8161
CCMO	NL71929.042.20
OMON	NL-OMON49393

Study results