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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27505

Bron
Nationaal Trial Register

Verkorte titel
OZPI

Aandoening

Peri-implantitis

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Mean peri-implant bleeding on probing (BoP)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

- 3- and 4-wall bone defects: the use of bone substitutes

- 0-, 1- and 2-wall defects: the use of systemic amoxicillin and metronidazole

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2020
Aantal proefpersonen:	123
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	15-11-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49393
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten