Treatment considerations for the surgical therapy of peri-implantitis

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON49393

Source
ToetsingOnline

Brief title
Surgical considerations in treating peri-implantitis

Condition

- Bacterial infectious disorders
- Soft tissue therapeutic procedures

Synonym
peri-implant disease, peri-implant infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: JSM Bench fee

Intervention

Keyword: Antibiotics, Bone substitutes, Peri-implantitis, Surgery

Outcome measures

Primary outcome

The main study parameter is mean peri-implant bleeding on probing (in %)

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) or progressive radiographical peri-implant bone loss

- Complication and adverse events

Study description

Background summary

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, such as resective and regenerative surgical therapy. 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. Depending on the configuration of the bone defect, a resective ,possibly supplemented with antibiotics, or or a regenerative surgical approach can chosen. The role of antibiotics towards the treatment of peri-implantitis still remains unclear in current literature. In addition, the use of regenerative bone substitutes seem to have a positive effect when used to treat peri-implant bone defects.

Study objective

The primary objective of this study is to examine clinical and radiographical parameters when executing:
- adjuvant antibiotic therapy versus no antibiotic therapy in the resective surgical treatment of 0-, 1- and 2-wall bone defects due to peri-implantitis
- regenerative versus resective surgical therapy of bone defects due to peri-implantitis.

The secondary objectives are:
To examine the microbiological consequences of:
- adjuvant antibiotic therapy versus no antibiotic therapy in the resective surgical treatment of 0-, 1- and 2-wall bone defects due to peri-implantitis
- regenerative versus resective surgical therapy of bone defects due to peri-implantitis.

To examine the effects of non-therapeutic parameters (such as implant-, patient- and lifestyle factors) on the success of the surgical treatment of peri-implantitis.

Study design

The study is designed as a randomized controlled trial.

Intervention

All patients with peri-implantitis will be treated in this study. First, all patients will undergo a nonsurgical treatment in which air-abrasive instruments are used to try and reinstate peri-implant health. After 3 months, the peri-implant health is re-evaluated. If no of insufficient improvement is noted, the patient will undergo the surgical treatment. In this protocol, the implant surface will be exposed and decontaminated using titanium curettes and air-abrasive instruments. Depending on the clinically assessed bone defect, the patient will be classified in 1 of 4 groups:

3- and 4-wall peri-implant bone defects:
1. Regenerative peri-implant surgery
2. Resective peri-implant surgery

0-, 1- and 2 wall bone defects:
3. Resective surgery without the use of adjuvant antibiotics
4. Resective surgery with the use of adjuvant antibiotics: amoxicillin and metronidazole.

Additionally, patients will receive oral self care instructions. Furthermore, patients are ought to use an antimicrobial mouth rinse containing 0,12% chlorhexidine and 0,05% cetylpyridinium chloride: 2 weeks, twice a day for 30 seconds. After 2 weeks, the sutures will be removed. The follow-up will be planned 3, 6, 9, and 12 months post-operatively.

Study burden and risks

Given the fact that the intervention consists of regular surgical peri-implantitis treatment, no additional risks are presumed. Alongside with the standarts appointments, (nonsurgical appointments, the surgery, suture removal after 2 weeks and 3, 6, 9 and 12 month appointments postoperatively) the patient will receive one additional appointment for research purposes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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;
- 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;
- significant contra-indications to the use of antibiotics due to other medicines;
- 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 bleeding on probing (< 20%), probing pocket depth < 6mm, plaque < 20%;
- active periodontal disease at the remaining dentition (probing pocket depth >= 6mm, bleeding on probing >= 20%) or insufficient oral hygiene (plaque >= 20%);
- use of antibiotics during the last 3 months.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-03-2020
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO

Date:	20-02-2020
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27505
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL71929.042.20
OMON	NL-OMON27505