Microbiological and clinical evaluation of different implant surface decontaminating procedures in the surgical treatment of peri-implantitis; a double blind placebo controlled randomized clinical study.

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

Summary

ID

NL-OMON33406

Source
ToetsingOnline

Brief title
Implant surface decontamination in peri-implantitis treatment

Condition

- Bacterial infectious disorders

Synonym
infection of the gingiva surrounding a dental implant, peri-implantitis

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,bedrijf,Dentaid

Intervention

Keyword: chlorhexidine, dental implant, microbiology, peri-implantitis

Outcome measures

Primary outcome

The main study parameters is microbial composition of the biofilm covering the

dental implant surface.

Secondary outcome

Secundary study parameters are:

- Modified bleeding index

- Probing pocket depth

- Suppuration on probing

- Microbiological composition of the peri-implant sulcus

- Radiographic marginal bone level on standardized intraoral radiographs

- Modified plaque index

- Implant calculus index

- Marginal soft tissue recession (REC)

- Implant failure, defined as implant mobility of previously clinically

osseointegrated implants and removal of non-mobile implants because of

progressive marginal bone loss or infection

- Complications and adverse events

- Patient satisfaction

Study description

Background summary

Peri-implantitis is a infectious disease that resides in the mucosa surrounding dental implants and also affects the supporting bone. Because the number of implants placed in everyday clinical practice is continuously increasing, is it reasonable to anticipate an increasing prevalence of peri-implantitis. This underlines the necessity for a predictable therapy. However, from the literature there is very little reliable evidence suggesting which could be the most effective interventions for treating peri-implantitis.

Study objective

The primary objective of this controlled clinical study is to evaluate the microbiological effect of chlorhexidine + CPC rinsing of the implant surface in the surgical treatment of peri-implantitis. The secondary objectives are to assess both the clinical and microbiological effectiveness of treatment of peri-implantitis.

Study design

The present study is a double-blind placebo-controlled randomized clinical trial.

Intervention

Implants with peri-implantitis lesions will be surgically exposed, followed by a mechanical cleansing using curettes and gauzes and cotton pellets soaked in saline followed by either 1 minute of rinsing with a placebo solution (saline with appearance of chlorhexidine) (control group) or 1 minute of chemical cleansing using 0,12% chlorhexidine + cetylpyridinium chloride (CPC) without alcohol (Perio-aid®) (test group). After 1 minute of saline rinsing the gingival flap will be returned slightly apical (in order to reduce pockets) and will be firmly sutured. For both groups the surgery is followed by 2 weeks of mouthrinses with 0,12% chlorhexidine + cetylpyridinium Chloride (CPC) without alcohol (Perio-aid®) two times daily during 30 seconds.

Study burden and risks

In addition to the regular follow-up visits (after 2 weeks, 3 and 6 months)

patients will have one additional appointment for research purposes only. During the appointments questionnaires have to be filled out and microbiological samples will be taken. Furthermore digital intra oral pictures are taken.

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

1) The patient is >= 18 years of age;
2) The patient has at least one endosseous implant in the oral cavity with clinical and radiographical signs of peri-implantitis. Peri-implantitis is defined as a loss of marginal bone >= 2 mm as compared to a fixed reference point on the dental implant, in combination with bleeding and/or suppuration on probing and a peri-implant probing depth >= 5 mm;
3) The implants have been exposed to the oral environment for at least two years;

4) The patient is capable of understanding and giving informed consent.

Exclusion criteria

1) Medical and general contraindications for the surgical procedures;
2) A history of local radiotherapy to the head and neck region;
3) Pregnancy and lactation;
4) Diabetes;
5) Systemic use of antibiotics during the last 3 months;
6) Long-term use of anti-inflammatory drugs;
7) Incapability of performing basal oral hygiene measures as a result of physical or mental disorders;
8) Active, uncontrolled periodontal pathology of the remaining dentition;
9) Local use of antibiotics or use of other anti-septic / antimicrobial therapies in the oral cavity during the last 3 months;
10) Use of mouthrinses;
11) Bruxism;
12) Implants placed in skin grafted areas;
13) Implants with bone loss due to other reasons than bacterial infection (e.g. loose screw, inadequate positioning of the implant);
14) Implants with bone loss exceding 2/3 of the length of the implant or implants with bone loss beyond the transverse openings in hollow implants;
15) Implant mobility;
16) Implants at which no postition can be identified where proper probing measurements can be performed;
17) Previous surgical treatment of the peri-implantitis lesions;
18) Previous non-surgical treatment of the peri-implantitis lesions during the last 6 months (scaling or curretage).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2009
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

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

No registrations found.

In other registers

Register	ID
CCMO	NL27147.042.09