Treatment of peri-implant mucositis; A randomized placebo controlled 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-OMON35044

Source
ToetsingOnline

Brief title
Treatment of peri-implant mucositis

Condition

- Bacterial infectious disorders

Synonym
infection of mucosa surrounding a dental implant, peri-implant mucositis

Research involving
Human

Sponsors and support

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

Intervention

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

Outcome measures

Primary outcome

The main study parameter is bleeding on probing;

Secondary outcome

- Modified bleeding index;

- Probing pocket depth (PPD);

- Modified plaque index;

- Implant calculus index;

- Marginal soft tissue recession (REC);

- Width of keratinized epithelium;

- Suppuration on probing;

- Microbiological status of the peri-implant sulcus;

- Radiographic marginal bone level on standardized intraoral radiographs.

Study description

Background summary

Peri-implant mucositis is an infectious disease that resides in the mucosa surrounding dental implants. If left untreated peri-implant mucositis might develop into peri-implantitis, an infectious disease residing in the mucosa surrounding dental implants which also affects the supporting bone. The number of implants placed in everyday clinical practice is continuously increasing, and it is anticipated that the prevalence of peri-implant mucositis will further increase. This underlines the necessity for a predictable therapy. Scientific literature provides very little evidence for an effective intervention protocol for treatment of peri-implant mucositis.

Study objective

The primary objective of this controlled clinical study is to evaluate the effect of chlorhexidine + CPC rinsing of the oral cavity for treatment of peri-implant mucositis.
The secondary objectives are to assess the effectiveness of peri-implant mucositis treatment and to assess the microbiology associated with peri-implant mucositis.

Study design

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

Intervention

Implants with peri-implant mucositis will be cleaned mechanically both supra- and submucosal, using plastic scalers and curettes, rubber cups and polishing paste, followed by 4 weeks of mouthrinses with a chlorhexidine solution (0.12% chlorhexidine + cetylpyridinium chloride (CPC) without alcohol (Perio-aid®)) or a placebo solution twice daily during 30 seconds;

Study burden and risks

All data will be collected during regular follow-up visits (according to the current umcg-protocol for treatment of peri-implant mucositis). Data collection will consist of clinical measurements, microbiologisch sampling, a questionnaire and digital intra-oral pictures.

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 signs of peri-implant mucositis. Peri-implant mucositis is defined as bleeding of the peri-implant mucosa on probing, with no signs of loss of supporting bone;
3) The implants have been exposed to the oral environment for at least one year;
4) The patient is capable of understanding and giving informed consent.

Exclusion criteria

1) Medical and general contraindications for the interventions;
2) A history of local radiotherapy to the head and neck region;
3) Diabetes;
4) Patients who are allergic to chlorhexidine;
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 during the last 6 weeks or during the course of the study;
11) Implants placed in skin grafted areas;
12) Peri-implantitis;
13) Implant mobility;
14) Implants at which no surface can be identified where proper probing measurements can be performed;
15) Previous treatment of peri-implant mucositis lesions during the last 6 months.

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):	02-07-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	16-06-2010
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	NL31615.042.10