Non-surgical treatment of peri-implantitis, a randomized, single blind, controlled trial

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Primary Objective: To investigate the additional effect of systemic antibiotics (amoxicillin 375 mg and metronidazole 250 mg) for non-surgical treatment of peri-implantitis in comparison to non-surgical treatment of peri-implantitis without the...

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

Summary

ID

NL-OMON41564

Source
ToetsingOnline

Brief title
Non-surgical treatment of peri-implantitis

Condition

- Bacterial infectious disorders

Synonym
Inflammation of the supporting tissues around a dental implant; infectious disease of the tissues around a dental implant

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Antibiotics, Dental hygiene, Non-surgical treatment, Peri-implantitis

Outcome measures

Primary outcome

The main outcome is the clinical attachment level (CAL).

Secondary outcome

Clinical parameters (pocket probing depth (PPD), bleeding on probing (BoP),

plaque-accumulation and bone loss) and microbiological parameters.

Study description

Background summary

Peri-implantitis is an inflammation of the peri-implant tissues with bleeding and/or suppuration on gentle probing (<0.25N) with a blunt instrument and crestal bone loss (Lang & Berglundh, 2011, Linde & Meyle, 2008). Swelling and redness of the marginal tissues may or may not be present, and there is usually no pain (Mombelli & Décaillet, 2011). In the worst case peri-implantitis may lead to loss of the dental implant.
The prevalence of peri-implantitis in subjects with dental implant is 28-56% (Zitzmann & Berglundh, 2008). With the increasing amount of dental implants, the amount of subjects with peri-implantitis is rising. Evaluation of excisting non-surgical treatment for peri-implantitis is therefore necessary (Renvert et al., 2008).

Study objective

Primary Objective:
To investigate the additional effect of systemic antibiotics (amoxicillin 375 mg and metronidazole 250 mg) for non-surgical treatment of peri-implantitis in comparison to non-surgical treatment of peri-implantitis without the adjunctive use of systemic antibiotics on the difference in clinical attachment level (CAL) between baseline and three and twelve months.
Secondary Objective(s):
The secondary objectives are to investigate the additional effect of systemic antibiotics (amoxicillin 375 mg and metronidazole 250 mg) for non-surgical treatment of peri-implantitis in comparison to non-surgical treatment of

peri-implantitis without the adjunctive use of systemic antibiotics on the differences in clinical (pocket probing depth (PPD), bleeding on probing (BoP), plaque-accumulation and bone loss) and microbiological parameters between baseline and three and twelve months.

In addition, the third objective is to compare the effect of systemic antibiotics on the differences in clinical and microbiological parameters between smokers and non-smokers and with the data of the periodontitis study with the same non-surgical treatment protocol.

Study design

Before the baseline appointment a short summary of the research is given during regular maintenance if the patient meets the inclusion criteria. When a patient wants to participate an appointment voor an intake is made. During the intake appointment an oral explanation of the study is given and the patient takes home the written information letter.
The study procedures for this randomised controlled trial are explicated below. Subsequent to the research protocol standard treatment procedures are performed. Please see amendment 1 of the research protocol for the description of the standard treatment protocol of peri-implantitis. Any diagnostic procedures or treatments are not postponed. Clinical measurements and anamneses are standard procedures during treatment appointments and will be adopted from the electronic health record of the subject.

First visit: Baseline (BL) signed informed consent; plaque samples from the deepest pocket of the target implant and from the deepest pockets of a natural teeth (if present)
Randomization (R) blinded for the dentist

Second visit: (T1) dental hygiene instruction
First intake of antibiotics for the test group, blinded for the dental hygienist

Third visit: (T2) non-surgical treatment quadrant I and VI

Fourth visit: (T3) non-surgical treatment quadrant II and III

Fifth visit: (T4) dental prophylaxis, removing all the staining, calculus and plaque

Sixth visit: (E1) evaluation, plaque samples

Seventh visit: (E2) evaluation after one year: plaque samples.

Intervention

Non-surgical treatment (mechanical cleaning of the implant surface) of peri-implantitis with adjunctive use of systemic antibiotics (amoxicillin 375mg and metronidazole 250mg three times a day for 7 days).

Study burden and risks

The burden and risks in this study are not different when compared to standard clinical treatment. The antibiotics used in this study are regularly used in dental practices and may cause side effects.

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

Dentate or edentate patients with at least one screw-type titanium implant;The implant should be in function for at least a period of 12 months;Peri-implant intraosseous defect with at least 3 mm depth measured from the neck. The extent of bone loss will be measured on the basis of peri-apical radiographs;Probing depth at the deepest site at least 5mm combined with bleeding and/or suppuration;Patient above 18 years of age;Psychological appropriateness;Signed Informed Consent obtained prior to start

Exclusion criteria

Patient with a history of taking systemic antibiotics in the preceding 3 months;Patient allergic to penicillin (amoxicillin) or metronidazole ;Systemic diseases like diabetes, HIV, Sjögren, SLE;Use of NSAID*s in the last 4 weeks;Current pregnancy or lactating;Mobile implants

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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2012
Enrollment:	48
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	amoxicillin
Generic name:	amoxicillin

Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	metronidazole
Generic name:	metronidazole
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	30-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2012-000565-21-NL
CCMO	NL39371.018.12