Systemic antibiotic therapy (amoxicillin plus metronidazole) as an adjunct to surgical treatment of peri-implantitis; a single blind randomized controlled study

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

Summary

ID

NL-OMON44733

Source
ToetsingOnline

Brief title
Amoxicillin plus metronidazole in surgical peri-implantitis treatment

Condition

- Bacterial infectious disorders

Synonym
infection of the soft and hard tissues surrounding dental implants, 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: Nobel Biocare,Nobel Biocare

Intervention

Keyword: amoxicillin, metronidazole, peri-implantitis

Outcome measures

Primary outcome

The main study parameter is full-mouth peri-implant bleeding score.

Secondary outcome

- Full-mouth periodontal bleeding score;

- Full-mouth peri-implant and periodontal suppuration on probing score (%);

- Full-mouth peri-implant and periodontal probing pocket depth;

- Full-mouth peri-implant and periodontal plaque score (%);

- Marginal soft tissue recession (REC);

- Radiographic marginal peri-implant bone level on standardized intraoral

radiographs;

- Microbiological composition of the peri-implant and periodontal area;

- 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.

Study description

Background summary

Peri-implantitis is an infectious disease that resides in the mucosa

surrounding dental implants and 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-implantitis 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 periimplantitis.

Study objective

The primary objective of this controlled clinical trial is to evaluate the clinical effect of systemic amoxicillin plus metronidazole therapy in conjunction with surgical treatment of peri-implantitis. The secondary objective is to assess the microbiological effectiveness of this peri-implantitis treatment approach.

Study design

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

Intervention

Implants with peri-implantitis (both test and control group) will be surgically treated (apically repositioned flap, bone recontouring, implant surface debridement and decontamination). The implant surface will be mechanically cleaned using plastic curettes and gauzes and cotton pellets soaked in saline. At the end of the treatment, the dental assistent will give the patients a bottle with 500 ml 0.12% chlorhexidine + 0.05% cetylpyridinium chloride mouthrinse without alcohol (Perio-Aid®) (to be used for 2 weeks, twice daily during 30 seconds) and an envelop containing general aftercare instructions related to the surgical procedure. The patients in de test group will additionally receive a recipe for medication consisting of 500 mg amoxicillin and 500 mg metronidazole to be taken every 8 hours for the following 7 days.

Study burden and risks

All data will be collected during regular treatment and regular follow-up visit (clinical parameters, microbiological samples, questionnaires, x-rays, impressions). Since the regular protocol for treatment of peri-implantitis is evaluated no additional risks are involved with participation in this study.

Contacts

Public
Universitair Medisch Centrum Groningen

Antonius Deusinglaan 1
Groningen 9713 AV
NL
Scientific
Universitair Medisch Centrum Groningen

Antonius Deusinglaan 1
Groningen 9713 AV
NL

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 the shoulder of the implant (the level at which the bone is normally located immediately after implant placement), in combination with bleeding and/or suppuration on probing and a peri-implant probing depth * 5 mm;
3) The implants have been in function 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) Uncontrolled diabetes (HbA1c > 7% or > 53 mmol/mol)
5) Mononucleosis infectiosa
6) Organic neurological disorders
7) Use of antibiotics during the last 3 months;
8) Known allergy to amoxicillin, metronidazole or chlorhexidine;
9) Long-term use of anti-inflammatory drugs (> 3 months);
10) Full edentulism (no remaining teeth, only implants)
11) Active periodontal disease at remaining dentition (PPD*6mm, bleeding*20%) and/or insufficient oral hygiene (plaque*20%)
12) Implants placed in areas augmented with autogenous bone from the crista iliac region;
13) Implants placed in skin grafted areas;
14) Implants with bone loss exceeding 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 position can be identified where proper probing measurements can be performed;
17) Previous surgical treatment of the peri-implantitis lesions;

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):	14-05-2014
Enrollment:	60
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:	18-10-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-03-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-08-2016
Application type:	Amendment
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
EudraCT	EUCTR2013-003940-21-NL
CCMO	NL46361.042.13