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Treatment of failing dental implants using deep cleaning with or without antibiotics

Submission date	Recruitment status	[_] Prospectively registered
08/11/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/11/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/07/2022	Oral Health	

Plain English summary of protocol

Background and study aims
Peri-implantitis is a destructive inflammatory process affecting the soft and hard tissues surrounding dental implants. Existing treatments are unpredictable at arresting the disease and current evidence does not support a gold-standard treatment. The use of systemic antibiotics, especially metronidazole or the combination of amoxicillin and metronidazole, in the non-surgical treatment of gum disease (periodontitis) has been widely investigated and in some cases has shown improvement. Therefore, antimicrobials have also been proposed for peri-implantitis treatment and are widely used by clinicians from all over the world, although the scientific evidence for their use is still inconclusive. The aim of this study is to evaluate the results of the use of amoxicillin and metronidazole in conjunction with non-surgical treatment, in comparison to non-surgical treatment alone.

Who can participate?
Patients aged 18 years and over with peri-implantitis

What does the study involve?
The patients are randomly assigned into one of the following treatments: submucosal debridement of the diseased implant (removal of dead or damaged tissue) with systemic antibiotics (amoxicillin and metronidazole three times a day for 7 days) and chlorhexidine mouthwash (two times a day for 4 weeks), or submucosal debridement with chlorhexidine mouthwash (two times a day for 4 weeks).

Possible risks and benefits of participating?
The burden and risks in this study are not different when compared to regular clinical treatment. The antibiotics used in this study are regularly used in dental practices and may cause side effects (e.g. upset stomach, diarrhea, yeast vaginal infections etc). Participants in both groups can expect the benefit of reduced peri-implant infection which can lead to better maintenance of the peri-implant tissue. This may result in less need for surgical treatments of peri-implant lesions and less implant failure in the future.

Where is the study run from?
Academic Centre for Dentistry Amsterdam (ACTA) (Netherlands)

When is the study starting and how long is it expected to run for?
September 2011 to March 2018

Who is funding the study
Academic Centre for Dentistry Amsterdam (ACTA) (Netherlands)

Who is the main contact?
Dr Angeliki Polymeri
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL 39371.018.12

Study information

Scientific Title
Non-surgical peri-implantitis treatment with or without systemic antibiotics: a randomized controlled clinical trial

Study objectives
The null hypothesis is that no differences exist between treatment approaches (non-surgical treatment alone vs non-surgical treatment with amoxicillin and metronidazole).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 30/10/2012, the ethical committee of the VU Medical Centre, Amsterdam (Medisch Ethische Toetsingscommissie, Academic Medical Center, University of Amsterdam. Meibergdreef 9 Postbus 22660, 1100 DD, Amsterdam, Netherlands; +31 (0)205667389; mecamc@amsterdamumc.nl), ref: NL 39371.018.12

Study design
Randomized controlled single-blinded clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peri-implantitis in patients with dental implants

Interventions
The study participants are recruited from the Department of Oral Implantology and Prosthodontics or the Department of Periodontology at the Academic Centre for Dentistry Amsterdam (ACTA). Using a block randomization design, patients who meet the inclusion criteria are assigned into one of the following treatment protocols: non-surgical treatment (NST) with amoxicillin 375 mg and metronidazole 250 mg (3 times a day for 7 days) and chlorhexidine mouthwash (0.12%, 2 times a day for 4 weeks, experimental group), or NST with chlorhexidine mouthwash (0.12%, 2 times a day for 4 weeks, control group).

Intervention Type
Mixed

Primary outcome(s)
Peri-implant probing depth (PIPD) measured to the closest mm from the mucosal margin to the base of the pocket using a periodontal probe (PCP-UNC 15; Hu-Friedy, Chicago, IL, USA). Measured at baseline and at 12 weeks.

Key secondary outcome(s))
Measured at baseline and 12 weeks:
1. Clinical attachment level (CAL) measured in mm using a stent with a fixed reference line with a periodontal probe (PCP-UNC 15; Hu-Friedy, Chicago, IL, USA)
2. Bleeding on probing (BoP), presence or absence, measured with a periodontal probe (PCP-UNC 15; Hu-Friedy, Chicago, IL, USA)
3. Suppuration on probing (SoP) presence or absence, measured with a periodontal probe (PCP-UNC 15; Hu-Friedy, Chicago, IL, USA)
4. Plaque Index (PI): the percentage of sites with plaque evaluated with visual inspection

Completion date
22/03/2018

Eligibility

Key inclusion criteria
1. Systemically healthy, adult patients (≥18 years old)
2. At least one failing dental implant (peri-implantitis)
3. The implant is in function for more than 1 year
4. Presents PIPD ≥5 mm, bleeding and/or suppuration on probing (BoP/SoP)
5. Marginal bone loss ≥3 mm detected radiographically

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
37

Key exclusion criteria
1. Use of systemic antibiotics within the past 3 months
2. Any chronic medical disease or condition
3. Known allergy to penicillin or metronidazole
4. Use of anti-inflammatory prescription medications within the past 4 weeks
5. Pregnancy or lactation
6. Presence of implant mobility

Date of first enrolment
19/12/2012

Date of final enrolment
23/03/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Centre for Dentistry Amsterdam (ACTA)
Gustav Mahlerlaan 3004

Amsterdam
Netherlands
1081 LA

Sponsor information

Organisation
Academic Center for Dentistry Amsterdam

ROR
https://ror.org/04x5wnb75

Funder(s)

Funder type
University/education

Funder Name
Academic Center for Dentistry Amsterdam

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Angeliki Polymeri (a.polymeri@acta.nl) for 2 years after the publication of the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/03/2022	18/07/2022	Yes	No
Participant information sheet		31/10/2012	29/11/2021	No	Yes
Protocol file			29/11/2021	No	No