Pocket irrigation in peri-implantitis treatment

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The aim of the present prospective cohort study is to assess the clinical and microbiological effects and patient-reported pain in the non-surgical treatment of peri-implantitis using a pocket irrigator/evacuator device

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25224

Bron
Nationaal Trial Register

Verkorte titel
GUMOZ

Aandoening

Peri-implantitis

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Mean peri-implant bleeding score (%)

Toelichting onderzoek

Achtergrond van het onderzoek

The most effective approach to treat peri-implantitis remains to be found. Recently, a new pocket irrigator/evacuator device, The Fluxion®, based on an alternated interplay between vacuum and fluid (water), has been introduced. A periodontal study showed decreased probing pocket depths and reduced bleeding on probing1. Moreover patients reported less pain after treatment compared to conventional treatment. Whether the pocket irrigator can be used for treatment of peri-implantitis seems unknown.

Doel van het onderzoek

The aim of the present prospective cohort study is to assess the clinical and microbiological effects and patient-reported pain in the non-surgical treatment of peri-implantitis using a pocket irrigator/evacuator device

Onderzoeksopzet

Start inclusion; march 2018
Data collection; march 2018 - march 2019
Data analysis; april 2019
Writing manuscript; june 2019
Submission; july 2019

Onderzoeksproduct en/of interventie

All patients receive extensive oral hygiene instructions (using an electric toothbrush, interdental brushes and floss (Oral-B® superfloss or Meridol® floss, at implants in the esthetic zone only) and mechanical non-surgical debridement of the remaining dentition and the supramucosal areas of the implants using ultrasonic instrumentation (EMS®) and hand instruments (scalers and curettes) in one session. The submucosal areas of the infected implants will be irrigated using the Pocketirrigator for 25 seconds per site (4 sites per implant), twice weekly during a period of 3 weeks.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-The patient is ≥ 18 years of age;
-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 progressive loss of marginal bone ≥ 2mm , as compared to the baseline radiograph (after placing the definitive restoration) in combination with bleeding and/or suppuration on probing (Lang and Berglundh 2011);
-The implants have been in function for at least two years;
-The patient is capable of understanding and giving informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Medical and general contraindications for the procedures;
- A history of local radiotherapy to the head and neck region;
- Uncontrolled diabetes (HbA1c < 7% or < 53 mmol/mol);
- Smoking
- Use of antibiotics during the last 3 months;
- Long-term use of anti-inflammatory drugs;
- Active periodontitis of the remaining dentition (PPD > 5 mm);
- Incapability of performing basal oral hygiene measures as a result of physical or mental disorders;
- 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;
- Implant mobility;
- Implants at which no position can be identified where proper probing measurements can be performed;
- Previous treatment of the peri-implantitis lesions during the last 3 months (scaling or curettage)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2018
Aantal proefpersonen:	24
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	16-05-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7746
Ander register	METC UMCG : METC2017.644

Resultaten