The Gum Irrigator, a new device in the treatment of peri-implantitis

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21056

Source
NTR

Health condition

Peri-implantitis

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)
Source(s) of monetary or material Support: University Medical Center Groningen (UMCG)

Intervention

Outcome measures

Primary outcome

The primary objective is to test the clinical effect of pocket irrigation with a new pocket irrigation device for non-surgical treatment of peri-implantitis.

Secondary outcome

Secondary objectives are

- to assess the microbiological effect of pocket irrigation with a new pocket irrigation device for non-surgical treatment of peri-implantitis;

- to assess patient-related outcomes.

Study description

Background summary

Rationale: Recently, a new apparatus has been developed for irrigation of periodontal and peri-implant pockets. The effectiveness of this Gum Irrigator for treatment of peri-implantitis has yet to be established in clinical studies.

Objective: The aim of the present cohort study is to test the efficacy of pocket irrigation with a new pocket irrigation device for non-surgical treatment of peri-implantitis.

Study design: The present study is a prospective cohort study (pilot study).

Study population: Adult patients (N=24) with at least one endosseous implant in the oral cavity with clinical and radiographical evidence of peri-implantitis will be included.

Intervention: Peri-implant pockets will be irrigated using the Gum Irrigator 2 times per week during a period of 3 weeks. Patients will receive oral hygiene instructions and the remaining dentition and supramucosal peri-implant areas will be cleaned with conventional methods (curettes and ultrasonic device) prior to submucosal irrigation. Clinical, microbiological and patient-centered measurements will be carried out prior to treatment and 3 months after treatment.

Main study parameters/endpoints: The main study parameter is the mean peri-implant bleeding score (%).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will have 6 (short) treatment appointments in addition to the other three appointments. No risks are involved with participation in the study.

Study objective

Submucosal irrigation with the Gum Irrigator will reduce bleeding on probing, pocketdepts and the amount of anearobic bacteria in the non-surgical treatment of peri-implantitis.

Study design

- Baseline

- 3 months

Intervention

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Contacts

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Eligibility criteria

Inclusion criteria

- The patient is at least 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 more than 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.

Exclusion criteria

- 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)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-03-2018
Enrollment:	24
Type:	Unknown

Ethics review

Positive opinion

Date:	01-02-2018
Application type:	First submission

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
NTR-new	NL6806
NTR-old	NTR6992
Other	Universitair Medisch Centrum Groningen (UMCG) : METc 2017/644

Study results