'A clinical study of the difference in the effect of pocket-irrigation in the treatment of peri-implantitis compared to a conventional therapy, the airflow: a randomized controlled trial'

Published: 18-05-2022
Last updated: 24-08-2024

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

Summary

ID

NL-OMON51972

Source
ToetsingOnline

Brief title
Pocket irrigation versus airflow in peri-implantitis treatment.

Condition

- Bacterial infectious disorders

Synonym
infection of the gums surrounding an implant

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: airflow, oxygen, peri-implantitis, pocket-irrigation

Outcome measures

Primary outcome

Peri-implant probing depth (PPD) is the primary parameter.

Secondary outcome

Secondary parameters include the amount of active metalloproteinase-8 proteins (MMP-8), color of the gingiva, plaque by the modified plaque index (MPI), BOP, suppuration, swelling and radiographical bone height in mm. Finally, the participant is asked to indicate the degree of pain during treatment on a numerical scale from 1 (no pain) to 10 (most possible pain). In addition, the following data is collected: gender, age, presence or absence of natural elements, the location of the implants and whether or not to smoke.

Study description

Background summary

Peri-implantitis is a common issue within the field of dental implantology. Despite decades of research on peri-implantitis treatments, no consensus is achieved on which treatment is most succesful. Recently, the Fluxion was launched onto the market. This device could treat peri-implantitis, using pocket-irrigation which is achieved by alternating vacuum and liquid infusion into the pocket. In previous research, the Fluxion is tested in combination with demineralised water as the liquid. Using an antimicrobial liquid instead of water could increase the effectivity of the Fluxion.

Study objective

The aim of this study is to assess the effectivity of the Fluxion, in combination with Bluem (Bluem, Bluem Europe, Zwolle, The Netherlands) and in combination with demineralised water. This aims to find a minimally invasive treatment for peri-implantitis.

Study design

The study is a randomised controlled trial in which 60 participants with a total of 60 implants (maximum of one implant per participant) will be randomly divided over the following three groups:

Experiment group 1: Fluxion + demineralised water
Experiment group 2: Fluxion + Bluem
Control group: conventional treatment using airflow (EMS AIRFLOW HANDY 3.0, EMS, Nyon, Swiss)

Prior to and six weeks after treatment respectively baseline and follow-up measurements of the clinical inflammatory parameters will take place. Radiographical bonelevels will be assessed at baseline and six months after therapy. The research will take place at Lassus Tandartsen Oisterwijk.

Intervention

The therapy in groups 1 and 2 consists of treatment of the implants with the Fluxion. The Fluxion is a box-like apparatus consisting of two compartments: one compartiment carrying the fluid which is used for infusion, and one compartiment in which the extracted matter ends up. A hose is connected to the box on one side, while on the other side a tip is attached to it. This tip is placed on the junction from the gingiva to the crown or to the implant in 6 sites, three buccal and three lingual or palatal. At each site, rapid alternations of fluid infusion and vacuum will take place for 7 seconds (one cycle). Demineralized water is used as a liquid for the participants from group 1 and Bluem for participants from group 2.
The participants from the control group are treated with airflow. Erythritol (AIR-FLOW PLUS, EMS, Nyon, Swiss) is used as the powder in the airflow, which is applied as standard.

Study burden and risks

Participants attend the practice three times. At the first appointment, the baseline measurement (clinical and radiographic) and the treatment are performed (20 min), at the second treatment the follow-up measurement of the clinical parameters (5 min) and at the third appointment the second X-ray is taken (5 min.). The research setting differs minimally from the regular care

for peri-implantitis patients, only the third appointment for a second X-ray is the extra burden that participants undergo.
The three treatments are minimally invasive and previous research has shown no risks with treatment with the Fluxion and the airflow.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

radiographical boneloss >= 2 mm surrounding an implant
presence of bleeding on probing or suppuration
age of at least 18 years old

Exclusion criteria

uncontrolled diabetes mellitus
usage of prescripted anti-inflammatory medication
presence of an allergic reaction to chlorhexidine
pregnancy
in case of an antibiotics therapy in the last 6 months

Study design

Design

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):	10-09-2022
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Fluxion
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	18-05-2022
Application type:	First submission

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
CCMO	NL75381.042.21