Effect of Delmopinol on treatment of inflammation around dental implants

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26876

Source
NTR

Health condition

Peri - implant mucositis / Peri-implantaire mucositis

Sponsors and support

Primary sponsor: ACTA
Source(s) of monetary or material Support: fund=initiator=sponsor=ACTA

Intervention

Outcome measures

Primary outcome

- Change in bleeding on Probing

Secondary outcome

- Plaque index

- Pocket probing depth

-Microbiological changes

Study description

Background summary

Peri- implant mucositis describes an inflammatory lesion that resides in the mucosa around osseointegrated dental implants. If left untreated, periimplant mucositis can lead to periimplantitis with accompanying bone loss.Current recommendation for treatment is mechanical debridement with or without antiseptics in addition to reinforcement of self performed oral hygiene. Antibiofilm agent Delmopinol has been suggested as an alternative to Chlorhexidine. However, there are still no studies to assess the effect of Delmopinol on treatment of peri-implant mucositis.

Study objective

There are no differences in clinical treatment outcome between mechanical debridement alone or mechanical debridement along with use of Delmopinol for a time period of 3 months in treating peri-implant mucositis.

Study design

-Screening

- Visit 1 treatment

- Visit 2 - 1 month after treatment

- Visit 3 - 3 month follow up

Intervention

- Mechanical debridement alone (along with placebo)

- Mechanical debridement along with Delmopinol mouthrinse

- Mechanical debridement along with Chlorhexidine mouthrinse

Contacts

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Eligibility criteria

Inclusion criteria

- Human adult patients with at least one screw type dental implant

- Bleeding on probing and / pus (< 0.25 N probing pressure)around at least one dental implant

- Implant in function at least 1 year, no radiographic boneloss beyond 2 mm compared to baseline radiograph

- Informed consent obtained after verbal and written information by investigator.

Exclusion criteria

- Osseointegrated dental implant with more than 2 mm boneloss as identified by comparing current radiograph with radiograph completed at time of prosthetic restoration.

- Patients smoking more than 20 sig/day

-Uncontrolled Diabetes Mellitus

- Untreated periodontitis

- Antibiotic/antiinflammatory use within last one month before start of study.

-Pregnancy and lactation

- psychiatric disorders

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2015
Enrollment:	85
Type:	Actual

Ethics review

Positive opinion

Date:	14-07-2015
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	NL5159
NTR-old	NTR5299
Other	EudraCT number // METC : 2014-004825-42 // NL.51404.029.15

Study results