Onderzoek naar relaties tussen nachtelijk knarsetanden en complicaties rond tandimplantaten.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27266

Source
Nationaal Trial Register

Health condition

Inflammation of peri-implant tissues, marginal bone loss, implant technical complications, suprastructure complications, implant mobility, loss of osseointegration.

Sponsors and support

Primary sponsor: Academisch Centrum Tandheelkunde Amsterdam (ACTA)
Source(s) of monetary or material Support: Sunstar Suisse SA

Intervention

Outcome measures

Primary outcome

Peri-implant inflammation and implant technical complications (modified gingival index, probing depth, implant mobility, marginal bone height, suprastructure complications, abutment complications, implant fracture, other complications)

Secondary outcome

None

Study description

Background summary

This prospective cohort study was designed to answer the question: “Is sleep bruxism a risk factor for (peri-)implant complications?”.The study is a single-centre, double- blind, prospective cohort study with a follow-up time of two years. 98 participants fulfilling inclusion criteria (planned treatment with implant-supported fixed suprastructure(s) and age 18 years or older) will be included. Sleep bruxism will be monitored at several time points as masticatory muscle activity during sleep by means of a portable single-channel electromyographic device. Our main outcomes are biological complications (i.e., related to peri-implant bleeding, probing depth, marginal bone height, quality of submucosal biofilm, and loss of osseointegration), and technical complications (i.e., suprastructure, abutment, implant body, or other).The results of this prospective cohort study will provide important information for clinicians treating bruxing patients with dental implants. Furthermore, it will contribute to the body of evidence related to the behaviour of dental implants and their complications under conditions of high mechanical loadings that result from sleep bruxism activity.

Study objective

Excessive mechanical load can cause complications of dental implants and their suprastructures, as well as the peri-implant soft and hard tissues. Sleep bruxism is considered as an important source of mechanical load in the oral environment. Therefore, it is hypothesized that sleep bruxism could be associated to implant and peri-implant complications.

Study design

Exam 1: at appointment of impression for suprastructure

- Peri-implant conditions

- Oral hygiene

- Quality of plaque

- Occlusal force

- Awake bruxism

- Smoking

- Occluding pairs

- Indicators of parafunctions

-Periodontal parameters

-Sleep bruxism (3 nights)

Exam 2: at appointment of placing the suprastructure, 2 weeks after exam 1

- Peri-implant conditions

- Oral hygiene

- Occlusal force

- Prosthetic characteristics

- Opposing element characteristics

- Indicators of parafunctions

- Periodontal parameters

Exam 3: 4 weeks (+/- 3 days) after exam 2

- Peri-implant conditions

- Implant technical complications

- Sleep bruxism (3 nights)

Exam 4: 6 weeks (+/- 1 week) after exam 3

- Peri-implant conditions

- Implant technical complications

- Quality of plaque

Exam 5: 9 months (+/- 2 weeks) after exam 4

- Peri-implant conditions

- Oral hygiene

- Quality of plaque

- Awake bruxism

- Smoking

- Occluding pairs

- Opposing element chracteristics

- Implant technical complications

- Indicators of parafunctions

- Periodontal parameters

- Sleep bruxism (3 nights)

Exam 6: 6 months (+/- 3 weeks) after exam 7

- Peri-implant complications

- Implant technical complications

Intervention

Placement of one or more dental implants which will support fixed suprastructures.

Contacts

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Eligibility criteria

Inclusion criteria

- Planned for treatment with implant-supported fixed suprastructure(s).
- 18 years of age or older.

Exclusion criteria

- Opposing teeth of implant-supported fixed suprastructure(s) are restored with removable artificial teeth.
- Patients categorized in the classes 3 or higher according to the ASA system for classification of physical status.
- Use of occlusal splint, mandibular repositioning appliance or any other bruxism mitigating device during sleep.
- Active periodontitis at the time of implant placement.
- Known allergy to GrindcareÂ® electrode material.
- Patients with a pacemaker.
- Swollen, infected or inflamed tissues or skin eruptions, e.g. phlebitis, varicose veins etc. in the placement area of the GrindcareÂ® electrode.
- Pregnant women will not be treated with dental implants. Pregnancy after placement of implants will not be a reason to stop participation of the subject in the study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2015
Enrollment:	100
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	18-12-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45030
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4790
NTR-old	NTR4930
CCMO	NL37715.029.11

Register	ID
OMON	NL-OMON45030

Study results