The implant-retained maxillary overdenture in the edentulous maxilla

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36571

Source
ToetsingOnline

Brief title
The implant-retained maxillary overdenture

Condition

- Other condition

Synonym
Denture problems

Health condition

Tandheelkundige aandoening: edentate bovenkaak met slecht functionerende bovenprothese

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: edentulous, Implant, Maxilla, Overdenture

Outcome measures

Primary outcome

Radiographic peri-implant boneheight changes

Secondary outcome

Implant survival

Overdenture survival

Clinical situation of the soft peri-implant tissues

Patiënt satisfaction

Study description

Background summary

A number of edentulous patients experiences problems with a conventional complete upper denture. Lack of retention and stability, together with an unpleasant feeling due to the palatal plate are the main complaints of these patients. An overdenture on endosseous implants gives the opportunity to improve retention and stability of the prosthesis and also have a reduction of the palatal plate.
There are a number of prospective studies on overdentures retained by implants in the maxilla (references). A study, in which different treatment options are compared to each other, has not been published yet. Besides patient*s satisfaction, clinical performance of the implants also is an important factor in the determination of success. Patient satisfaction has rarely been part of a prospective study on implant-retained maxillary overdentures.

Study objective

The aim of the study is to compare the treatment with four or six implants in combination with an overdenture for patients with lack of retention and stability of their complete upper denture.
The clinical function of the implants and overdenture, radiographic peri-implant boneheight changes and patient satisfaction are part of this prospective randomized trial.

Study design

Group 1: There is sufficient bone height in the frontal region of the edentulous maxilla (>10 mm) and above the maxillary sinus (>5 mm), bone width is sufficient (>5 mm). If needed a sinus elevation procedure with intra-oral bone will be performed in the same session as the implantation procedure. The patient has an edentulous mandible and four implants are inserted in the interforaminal region.

Group 1a: Four implants of at least 10 mm length are inserted in the frontal area of the maxilla. (test group)

Group 1b: Six implants of at least 10 mm length are inserted in the frontal area of the maxilla. (control group)

Groep 2: There is insufficient bone height in the frontal region of the edentulous mandible (<10 mm) and above the maxillary sinus (< 5 mm), bone width of the maxilla is less than 5 mm. A sinuselevation procedure with bone from the iliac crest is performed in a separate session. After a period of three months of wound healing the implant procedure is performed. The patient has an edentulous mandible and four implants are inserted in the interforaminal region.

Group 2a: four implants (two at the left side and two at the right side) are inserted in the lateral region of the maxilla. (test group)

Group 2b: six implants (two at the left side and two at the right side) are inserted in the lateral region of the maxilla. (control group)

Intervention

The intervention is that the test group will receive four implants in the edentulous maxilla in combination with an overdenture. The control group will receive six implants and an overdenture.

Study burden and risks

There will be no extra risks for the patient in the procedure with four

implants compared to the standard procedure with six implants in the edentulous maxilla. Patients have to visit us two times more for the evaluation of the implants and the overdenture, the evaluation of the soft peri-implants tissues and radiographic peri-implant bone height change and for the evaluation of the patient satisfaction.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- at least one year edentulous in the upper jaw
- problems with retention and stability of the conventional complete denture and/or unpleasant feeling due to extended palatal plate of the denture
- The patient should have an edentulous mandible

Exclusion criteria

- no history of preprosthetic surgery in the upper jaw
- no medical contraindications for surgery
- patient does smoke (or is not willing to give up smoking six weeks before surgery)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	03-01-2012
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	NL32503.042.11
Other	NTR (TC = 2969)