Implants in the edentulous maxilla to support an overdenture.

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The is no difference between an overdenture on 4 implants (test group) compared with an overdenture on 6 implants (control group).

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22852

Bron
NTR

Aandoening

Overdenture, implants, edentulous maxilla.
Overkappingsprothese, implantaten, edentate bovenkaak

Ondersteuning

Primaire sponsor: Universitair Medisch Centrum Groningen
afd. Centrum voor Tandheelkunde en Mondzorgkunde
Overige ondersteuning: Niet van Toepassing

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Radiographic peri-implant boneheight changes.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

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.

Doel van het onderzoek

The is no difference between an overdenture on 4 implants (test group) compared with an overdenture on 6 implants (control group).

Onderzoeksopzet

1. T0 clinical and radiographical examinations at time of placement of overdenture;

2. T12 clinical and radiographical examinations one year after placement of overdenture.

Onderzoeksproduct en/of interventie

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)

Group 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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. At least one year edentulous in the upper jaw;

2. Problems with retention and stability of the conventional complete denture and/or unpleasant feeling due to extended palatal plate of the denture.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. No history of preprosthetic surgery in the upper jaw;

2. No medical contraindications for surgery;

3. Patient does smoke (or is not willing to give up smoking six weeks before surgery).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2011
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2828
NTR-old	NTR2969
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

Slot W, Raghoebar GM, Vissink A, Huddleston Slater JJ, Meijer HJ, A systematic review of implant-supported maxillary overdentures after a mean observation period of at least 1 year. J Clin Periodontol. 2010 Jan;37(1):98-110.