A comparison between 2 and 4 implants in the edentulous maxilla supporting an overdenture; 1-year results from a randomized controlled trial.

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The aim of the study is comparison of two and four dental implants supporting an overdenture in the upper jaw for patients who experience problems with retention and stability of the upper denture.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46717

Source
ToetsingOnline

Brief title
2 and 4 implants supporting a maxillairy overdenture

Condition

- Other condition

Synonym
Malfunctional denture in the upper jaw

Health condition

Het slecht functioneren van een prothese in de bovenkaak

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

Peri-implant bone height changes

Secondary outcome

Implant survival, overdenture survival, the clinical condition of the

peri-implant mucosa, masticatory efficiency, patient

satisfaction and overall state of health

Study description

Background summary

A number of edentulous patients experiences problems with a conventional complete upper denture. Lack of retention and stability and an increased gagging reflex is the main complaint of these patients. An overdenture on endosseous implants gives the opportunity to improve retention and stability of the prosthesis and reduce the coverage of the palate.

Study objective

The aim of the study is comparison of two and four dental implants supporting an overdenture in the upper jaw for patients who experience problems with retention and stability of the upper denture.

Study design

A prospective randomized controlled trial

Intervention

The testgroup will get 2 implants in combination with an overdenture and barsuprastructure in the maxilla.
The controlgroup will get 4 implants in combination with an overdenture and barsuprastructure in the maxilla.

Study burden and risks

De standaard behandeling van minimaal vier implantaten wordt vaak uitgevoerd bij patiënten met klachten aangaande retentie en stabiliteit van de volledige bovenprothese. De behandeling van twee implantaten levert eenzelfde of minder risico op, gezien er minder implantaten worden geplaatst dan tijdens de standaard behandeling.
De patiënten krijgen één extra afspraak, 1 maand na plaatsen van de overkappingsprothese. Het tweede meetmoment vindt plaats tijdens de standaard controle, 1 jaar na het plaatsen van de overkappingsprothese. Tijdens deze bezoeken worden de klinische en radiologische metingen en de kauwtest verricht en kunnen de vragenlijsten met betrekking tot de patiënt tevredenheid worden ingevuld.

The standard treatment of a minimum of four implants is performed regularly in patiënts with complaints of retention and stability of the full arch denture in the upper jaw. The treatment with two implants results in similar or less risc, due to the placing of less implants than during standard treatment.
Patients get one extra appointment, one month after placing the overdenture. The second measurement will take place during standard check-up, one year after placing the overdenture. During these visits, the clinical and radiological measurements, the chewing test and questionnaires
regarding patient satisfaction can be completed.

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
Patient is endentulous in the lower jaw
Patient gives written consent for entering the trial

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-02-2018
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	dental implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-01-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-01-2019
Application type:	Amendment
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

ID: 21899
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63532.042.17
OMON	NL-OMON21899