

Two or four implants as a support for an overdenture in the upper jaw.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21899

Source

Nationaal Trial Register

Health condition

Overdenture, Maxilla, Implant

Sponsors and support

Primary sponsor: University Medical Center Groningen

Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

Peri-implant bone height changes.

Secondary outcome

1. Implant survival;
2. Overdenture survival;

3. The clinical condition of the peri-implant mucosa;
4. Masticatory efficiency and patient satisfaction.
5. Overall health

Study description

Background summary

Background

A number of edentulous patients experience problems with a conventional complete upper denture. Lack of retention and stability and an increased gagging reflex are the main complaints 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.

Objective

The aim of the present study is to compare overdentures that are supported by two and four implants, for patients who experience problems with retention and stability of the upper denture.

Study design:

A prospective randomized controlled trial.

Study population:

Healthy persons aged 18 years or older.

Intervention: The testgroup will get 2 implants with a bar structure in combination with an overdenture in the maxilla.

The controlgroup will get 4 implants with a bar structure in combination with an overdenture in the maxilla.

Primary study parameters/outcome of the study: Peri-implant bone height changes.

Secondary study parameters/outcome of the study: Implant survival, overdenture survival, the clinical condition of the peri-implant mucosa, masticatory efficiency, patient satisfaction and overall health impact

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

According to the literature, treating patients with an overdenture in the maxilla on four implants is the standard treatment. Treating patients with two implants gives similar or less risk, because less implants are placed compared to standard treatment.

The patients will get to additional appointments for check-up. The first 1 month after placement of the overdenture and the second 1 year after placement of the overdenture. During these visits, the clinical and radiological measurements, the chewing test and questionnaires regarding patient satisfaction can be completed.

Study objective

An overdenture supported by two implants doesn't show more peri-implant bone loss after one year than an overdenture supported by four implants.

Study design

Prospective randomised controlled trial.

Intervention

The testgroup will get 2 implants with a barmesostructure in combination with an overdenture in the maxilla.

The controlgroup will get 4 implants with a barmesostructure in combination with an overdenture in the maxilla.

Contacts

Public

UMCG afd. MKA-chirurgie

P. Onclin
Groningen
The Netherlands
050-361 1054

Scientific

UMCG afd. MKA-chirurgie

P. Onclin
Groningen
The Netherlands
050-361 1054

Eligibility criteria

Inclusion criteria

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
3. Patient is edentulous in the lower jaw.

Exclusion criteria

1. history of preprosthetic surgery in the upper jaw;
2. medical contraindications for surgery;
3. smoking (or isn't willing to give up smoking six weeks before surgery);
4. 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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2017
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion	
Date:	26-09-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46717
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6561
NTR-old	NTR6742
CCMO	NL63532.042.17
OMON	NL-OMON46717

Study results

Summary results

N/A