

The upperdenture on a bar or pushbuttons?

No registrations found.

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

Summary

ID

NL-OMON29628

Source

NTR

Health condition

Overdenture, maxilla, locator, bar

Overkappingsprothese, bovenkaak, locator, staaf

Sponsors and support

Primary sponsor: University Medical Center Groningen

Source(s) of monetary or material Support: fund = initiator = sponsor

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.

Study description

Background summary

Background of the study:

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.

Objective of the study:

The aim of the study is comparison of two attachment systems with four dental implants and overdentures in the upper jaw 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 4 implants with a ballmesostrucure in combination with an overdenture in the maxilla. The controlgroup will get 4

implants with a ballmesostructure 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 and patient satisfaction.

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

According to the literature, both treatments are common treatments for patients with complaints of retention and stability of the upper denture. So there is no additional risk for the patients participating in the study. 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

A ball mesostructure is easier to clean and will give better results than a bar mesostructure. Also, the technical procedure is easier and will satisfy the clinician and patient more.

Study design

Prospective randomised controlled trial.

Intervention

The testgroup will get 4 implants with a ballmesostructure in combination with an overdenture in the maxilla.

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

Contacts

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Eligibility criteria

Inclusion criteria

At least two years 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 edentulous in the lower jaw.

Exclusion criteria

1. No history of preprosthetic surgery in the upper jaw;
2. No medical contraindications for surgery;
3. Patient does not smoke (or is willing to give up smoking six weeks before surgery);
4. 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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2013
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion	
Date:	23-01-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38882
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3667

Register

NTR-old

CCMO

ISRCTN

OMON

ID

NTR3813

NL43293.042.13

ISRCTN wordt niet meer aangevraagd.

NL-OMON38882

Study results

Summary results

N/A