

A comparison between bar versus ball mesostructures in the maxilla to support an overdenture; 1-year results from a randomized controlled trial.

Published: 08-05-2013

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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.

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

Summary

ID

NL-OMON38882

Source

ToetsingOnline

Brief title

Bar of ball mesostructure to support a maxillary 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: bar, Locator, 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 and patient satisfaction

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 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

Intervention

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

Study burden and risks

According to the literature, both treatmentst 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.

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 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

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:	Recruitment stopped
Start date (anticipated):	01-09-2013
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	ball suprastructure
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date: 08-05-2013

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

ID: 29628

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL43293.042.13
OMON	NL-OMON29628