# Implants in the edentulous maxilla to support an overdenture.

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON22852

**Source**
NTR

**Health condition**

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

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
afd. Centrum voor Tandheelkunde en Mondzorgkunde
**Source(s) of monetary or material Support:** Niet van Toepassing

### Intervention

### Outcome measures

**Primary outcome**

Radiographic peri-implant boneheight changes.

**Secondary outcome**

1. Implant survival;

2. Overdenture survival;

3. Clinical situation of the soft peri-implant tissues;

4. Patient satisfaction.

# Study description

### Background summary

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.

### Study objective

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

### Study design

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

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

### Intervention

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).

# Contacts

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# 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.

## Exclusion criteria

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).

# 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): | 01-09-2011 |
| Enrollment: | 100 |
| Type: | Anticipated |

## Ethics review

Not applicable
Application type: Not applicable

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL2828 |
| NTR-old | NTR2969 |
| Other | : |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

## Study results

**Summary results**
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.