# Implant-supported maxillary overdentures: a 10-years evaluation

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON21260

**Source**
Nationaal Trial Register

**Brief title**
Maxillary overdentures with 10-years follow-up

**Health condition**

Edentulous patients with retention and stability problems of conventional upper denture

### Sponsors and support

**Primary sponsor:** University Medical Center Groningen
**Source(s) of monetary or material Support:** UMCG

### Intervention

### Outcome measures

**Primary outcome**

Peri-implant bone level changes in 10 years

**Secondary outcome**

Implant survival, restoration survival, clinical parameters, patient satisfaction

# Study description

### Background summary

Edentulous patients often experience problems with their complete dentures. The increase in comfort for patients wearing an implant-supported overdenture versus a conventional denture is striking, especially for those who suffer from lack of stability and retention. Since results of 6 bar-connected implants and 4 bar-connected seem comparable and with favourable one-year and 5-years results, the question raises whether this premise will hold after a longer evaluation period and whether 6 implants are needed to support an implant-retained maxillary overdenture. Yet, there are no randomized controlled trials of ≥10 years in which the treatment outcome of 4-implant maxillary overdentures are compared with 6-implant maxillary overdentures. Therefore, the purpose of this 10-years randomized controlled trial is to assess the treatment outcome (implant survival, overdenture survival, peri-implant health, radiographic bone height changes, patients' satisfaction and biological/technical complications) of maxillary overdentures supported by 4 or 6 dental implants in the maxillary region.

### Study objective

Simular outcomes in patients with 4 implants compared with patients with 6 implants with respects to peri-implant bone level stability

### Study design

10-years follow-up evaluation

### Intervention

Collecting 10-years follow-up data

# Contacts

**Public**
University Medical Center Groningen
Henny J.A. Meijer

+31503613840
**Scientific**
University Medical Center Groningen
Henny J.A. Meijer

+31503613840

# Eligibility criteria

## Inclusion criteria

- at least 18 years of age;
- capable of understanding and giving informed consent;
- at least one year edentulous in the maxilla and mandible;
- bone dimensions at least 12 mm in height and at least 5 mm in width to reach initial stability of the implant;
- sufficient interocclusal space for a bar-supported attachment system.

## Exclusion criteria

Excluded were patients with ASA score ≥III, who were smoking, with a history of radiotherapy in the head and neck region or a history of pre-prosthetic surgery or previous implant placement.

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-10-2021 |
| Enrollment: | 100 |
| Type: | Actual |

## IPD sharing statement

**Plan to share IPD:** Undecided

**Plan description**
Upon reasonable request

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 14-09-2021 |
| Application type: | First submission |

# 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 | NL9729 |
| Other | METC UMCG : M18.224571 (Metc 2018/067) |

# Study results

**Summary results**
Maxillary overdentures supported by four or six implants: 10-years results from a randomized controlled trial