# Maxillary sinus floor augmentation with autogenous bone and bovine bone mineral in the resorbed maxilla: a 1-year multicentre, split-mouth, randomized clinical trial

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The succes of dental implants placed in the augmented maxillary sinus by using a bovine bone mineral (BBM) with some locally harvested AB chips, is superior to, implants placed in augmented sinuses with solely autogenous bone.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON27028

**Bron**
Nationaal Trial Register

**Verkorte titel**
Cerabone Study

**Aandoening**

Maxillary sinus floor augmentation, autogenous bone, bovine bone material, oral implants

### Ondersteuning

**Primaire sponsor:** -University Medical Centre Erasmus MC, Rotterdam,<br>
-St. Anna Hospital, Geldrop<br>
-Catharina Hospital, Eindhoven.<br>
-St. Antonius Hospital, Nieuwegein
**Overige ondersteuning:** Straumann AG, Basel, Switzerland

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Success of the MSFA procedure determined by 1-year clinical performance of dental implants placed in augmented maxillary sinus

# Toelichting onderzoek

### Achtergrond van het onderzoek

Insufficient bone height is a common problem in the reconstruction of the edentulous posterior maxilla prior to the placement of dental implants. To create sufficient height, maxillary sinus floor augmentation (MSFA) is performed with autogenous bone (AB) or bone substitutes, such as bovine bone mineral (BBM). AB is considered the golden standard, but has major drawbacks such as fast resorption, limited availability and considerable morbidity at the donor side. BBM might perform better then AB, but there is a lack of randomized controlled trials.

A bilateral MSFA will be performed in 46 patients with a resorbed posterior maxilla. MSFA will be performed randomly with AB harvested from mandibular ramus on one side and with BBM, mixed with some locally harvested AB chips (via existing incision for sinus elevation) on the other side.

Implant placement will be performed 4-6 months after augmentation. Second-phase surgery and implant loading will be performed 4-6 months thereafter.

The aim of this study is to assess the success of MSFA determined by 1-year clinical performance of dental implants placed in augmented maxillary sinus with solely AB versus BBM with some locally harvested AB chips.

### Doel van het onderzoek

The succes of dental implants placed in the augmented maxillary sinus by using a bovine bone mineral (BBM) with some locally harvested AB chips, is superior to, implants placed in augmented sinuses with solely autogenous bone.

**Onderzoeksopzet**

Intake, MSFA procedure, check up after two weeks, implant placement procedure, check up after two weeks, second-phase surgery, 1 month after placement of final prosthesis, 1 year after placement of final prosthesis

**Onderzoeksproduct en/of interventie**

The study will be designed as a multicenter, split-mouth, randomized split mouth study.: Randomisation will be carried out between two sides:

1. AB harvested from mandibular ramus

2. BBM, Cerabone (Cerabone, Botiss Dental, Berlin, Germany) mixed with approximately one-fifth locally harvested AB chips (via existing incision for sinus elevation).

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-18 years and older

-In need for bilateral dental implant placement in the posterior maxilla

-Bone height should be more then 2 mm and less then 5 mm

-Bone width should be over 5 mm

-Enough volume of the mandibular ramus to facilitate bone harvesting.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Presence of clinical active periodontal disease

Acute inflammatory oral disease

Smoking

Uncontrolled diabetes

A history of radiotherapy in the head- and-neck region or current chemotherapy

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Anders |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Actieve controle groep |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 21-08-2017 |
| Aantal proefpersonen: | 46 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 09-09-2017 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL6499 |
| NTR-old | NTR6686 |
| Ander register | NL59578.078.16 : MEC 2017-001 |

## Resultaten

**Samenvatting resultaten**

N/A