

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 success 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

NTR

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,
-St. Anna Hospital, Geldrop
-Catharina Hospital, Eindhoven.
-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 than 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 success 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 than 2 mm and less than 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:	Geneesmiddel

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