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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27028

Source
Nationaal Trial Register

Brief title
Cerabone Study

Health condition

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

Sponsors and support

Primary sponsor: -University Medical Centre Erasmus MC, Rotterdam,
-St. Anna Hospital, Geldrop
-Catharina Hospital, Eindhoven.
-St. Antonius Hospital, Nieuwegein
Source(s) of monetary or material Support: Straumann AG, Basel, Switzerland

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

-Volumetric changes of the bone graft

-Histological evaluation

-Micro-computed tomography (µCT) analysis

-Patient satisfaction and pain scores regarding MSFA

-Implant survival

-Implant success

-Prosthetic success

-Complications

-Plaque, gingival and bleeding indices

-Pocket probing depth

-Peri-implant radiographic bone levels

-Volumetric changes of the bone graft

-Patients satisfaction with implant placement and prosthesis

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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).

Contacts

Public

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Eligibility criteria

Inclusion criteria

-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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-08-2017
Enrollment:	46
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-09-2017
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	NL6499
NTR-old	NTR6686
Other	NL59578.078.16 : MEC 2017-001

Study results

Summary results
N/A