Sinus floor augmentation with microstructured BCP granules

No registrations found.

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

Summary

ID

NL-OMON29673

Source
Nationaal Trial Register

Brief title
SinusBCP

Health condition

Maxillary sinus floor augmentation, sinus pneumatization, maxillary atrophy, maxillaire sinusbodem elevatie, maxillaire atrophy, sinus penumatisatie

Sponsors and support

Primary sponsor: University Medical Center Utrecht, Department of Oral and Maxillofacial Surgery & Special Dentistry
Source(s) of monetary or material Support: - Kuros Biosciences
- European Union’s Horizon 2020 research and innovation program (grant agreement no. 674282)

Intervention

Outcome measures

Primary outcome

Percentage of new bone formation in the augmented sinus floor by histomorphometrical

analysis of biopsy specimens at 5 months of follow up.

Secondary outcome

- Implant survival rate and adverse events during 17 months of follow up.

- Augmented bone height as measured by CBCT at 5, 11 and 17 months of follow up.

- Implant stability quotient (ISQ) as measured by resonance frequency analysis (RFA) at 5 months (primary stability) and 11 months of follow-up.

- Scoring of gingival index, supra-gingival plaque index, and dichotomous bleeding index 17 months after surgery.

- Probing depth of implant and adjacent teeth (buccal, palatinal, distal, mesial) at 17 months after surgery.

- Pain by the Visual Analogue Scale (VAS-score)

Study description

Background summary

Loss of teeth and molars is generally followed by alveolar bone resorption, which may lead to reduced bone height in the posterior maxilla. In order to regain bone volume in the posterior maxilla to allow for the placement of dental implants, maxillary sinus floor elevation is a common procedure. In this procedure, autologous bone graft is implanted on the bony floor of the maxillary sinus to increase the bone height. However, since the harvesting of autologous bone is associated with pain and donor-site morbidity, alternative strategies are being pursued. The current study compares a commercial bone graft substitute material called MagnetOs Granules versus the gold standard bone autograft in the maxillary sinus floor elevation procedure. The goal of this clinical trial is to determine whether MagnetOs Granules, a biphasic calcium phosphate ceramic with submicron surface topography, is an effective alternative to the gold standard for sinus floor elevation. A total of 30 patients will be included at the UMC Utrecht of which 15 patients shall be treated with MagnetOs Granules and 15 patients with bone autograft. Study endpoints will include the analysis of new bone formation in the sinus floor from biopsies, micro-CT analysis, implant stability measurements, gingival health check, patient-reported pain and adverse events, during a follow-up period of 17 months.

Study objective

Microstructured BCP might be a suitable substitute to autologous bone graft in the sinus floor augmentation procedure

Study design

0, 5, 11, 17 months post-surgery

Intervention

Patients will undergo sinus floor augmentation with either autologous bone graft or with micro-structured BCP granules.

Contacts

Public
Department of Oral and Maxillofacial Surgery, UMC Utrecht

A.J.W.P. Rosenberg
Heidelberglaan 100

Utrecht 3584 CX
The Netherlands
+31 88 75 577 51
Scientific
Department of Oral and Maxillofacial Surgery, UMC Utrecht

A.J.W.P. Rosenberg
Heidelberglaan 100

Utrecht 3584 CX
The Netherlands
+31 88 75 577 51

Eligibility criteria

Inclusion criteria

- Male or female patients aged 18-75 years

- Patient is willing to give informed consent to participate in the study

- Patient qualifies for sinus augmentation surgery

- Presence of a unilateral or bilateral (partial) maxillary edentulism involving the

premolar/molar areas

- Presence of a residual posterior maxillary bone height between 2 and 6 mm

Exclusion criteria

- Maxillary sinus pathology

- Presence of a local or systemic disease or treatment affecting bone formation

- Contamination of the (area around the) operative field

- Periodontitis

- Infectious diseases

- Bone metabolic disease

- Neurological disorders that could influence mental validity

- Smoking

- Female of child bearing potential, who are pregnant or breast-feeding

- Cancer therapy including immune-suppression, chemotherapy and radiation

- Patients in which primary stability could not be established

- Previous entry into this study or participation in any other clinical trial within 30 days

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):	06-02-2018
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-02-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47531
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6434
NTR-old	NTR7225
CCMO	NL61242.041.17
OMON	NL-OMON47531

Study results