

Microstructured BCP granules as bone graft substitute in maxillary sinus floor augmentation with two-stage implant placement

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON47531

Source

ToetsingOnline

Brief title

Sinus floor augmentation with microstructured BCP granules

Condition

- Head and neck therapeutic procedures

Synonym

atrophic posterior maxilla, reduced bone height of the sinus floor

Research involving

Human

Sponsors and support

Primary sponsor: MKA chirurgie

Source(s) of monetary or material Support: Ministerie van OC&W, Kuros Biosciences B.V.

Intervention

Keyword: Bone substitute, Calcium phosphate ceramic, Maxillary sinus floor augmentation

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, distal, palatinal, mesial) at 17 months after surgery.
- Pain by the Visual Analogue Scale (VAS-score) at visit 2 (baseline) to 6.

Study description

Background summary

Loss of teeth and molars is generally followed by resorption of the alveolar bone. Severe alveolar bone resorption is often a major obstacle for dental implant insertion for replacement of molars. In order to regain sufficient bone quantity and quality for the installation of oral implants in the posterior maxilla, the sinus floor augmentation procedure can be performed. In this procedure, access to maxillary sinus is gained through the lateral wall of the

alveolar ridge. Subsequently the sinus floor is augmented by lifting the sinus mucosa and placing graft material within the created space on the sinus floor. The use of autogenous bone in sinus floor augmentations is the golden standard. However, the surgical removal of autologous bone requires an additional surgical site and comes with a distinct set of potential complications, including chronic pain of the donor site. Calcium phosphate ceramics (CaP) have been developed as synthetic bone graft substitutes that eliminate the need for autogenous bone harvesting. MagnetOs is a novel biphasic CaP developed by Kuros Biosciences that due to an instructive microstructured surface has osteoinductive capacity and can induce de novo bone formation. Therefore, MagnetOs granules may form a very suitable alternative to autogenous bone graft for the sinus floor augmentation procedure.

Study objective

The primary objective is to determine the efficacy of MagnetOs BCP granules in inducing adequate bone quantity and quality to support endosseous dental implants in the two-staged maxillary sinus floor augmentation procedure. Herein the treatment will be compared to sinus floor augmentation with autologous bone graft.

Secondary objective is to assess the clinical performance, functional performance (of dental implants) and pain with the use of MagnetOs BCP granules in sinus augmentation as compared to treatment with autologous bone graft.

Study design

This is a prospective clinical study to evaluate efficacy of MagnetOs BCP granules in sinus floor augmentation. The study is designed as a controlled open- label, randomized, non-inferiority trial.

Intervention

Patients will undergo sinus floor augmentation with MagnetOs BCP granules as bone graft substitute or with autologous bone graft. A biopsy will be obtained from the maxilla before implant placement.

Study burden and risks

The burden is that all subjects will have to undergo additional examinations during the regular follow-up visits. The extra examinations will include the taking of a biopsy at 5 months, measurements of implant stability at 5 months and 11 months post-surgery and a CBCT scan at 17 months post-surgery. The potential risks related to this study are associated with normal sinus augmentation surgery such as pain, infection and failure of osseointegration of dental implants. Although safety and efficacy have been determined through

pre-clinical animal studies (biocompatibility, safety, efficacy), risk analyses and clinical evaluations based on literature and high similarity with existing calcium phosphate bone void filler products, safety and efficacy have not yet been shown in a clinical study. Although MagnetOs is already available on the EU market, the current study will be the first study to evaluate MagnetOs in human subjects and therefore the study will bear a moderate risk.

The direct benefit for the participating subjects is that micro-structured BCP granules are a bone graft substitute and therefore no autogenous bone will have to be harvested for the sinus augmentation procedure. This removes the disadvantages of bone graft procedures from the treatment, including a secondary operation site and the risk of donor site morbidities like chronic pain and neurological complications. For some patients that will undergo an additional procedure in the maxilla that requires autogenous bone, a smaller amount of bone will be harvested when MagnetOs is used in the sinus.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- * Male or female patients aged 18-75 years
- * 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
- * Patient qualifies for sinus augmentation surgery
- * Smoking *10 cigarettes per day

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
- * Pregnant or breast-feeding women
- * 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
- * Smoking >10 cigarettes per day

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 06-02-2018
Enrollment: 30
Type: Actual

Medical products/devices used

Generic name: MagnetOs granules
Registration: Yes - CE intended use

Ethics review

Approved WMO
Date: 06-09-2017
Application type: First submission
Review commission: METC NedMec
Approved WMO
Date: 12-12-2017
Application type: Amendment
Review commission: METC NedMec
Approved WMO
Date: 13-12-2017
Application type: Amendment
Review commission: METC NedMec
Approved WMO
Date: 20-11-2018
Application type: Amendment
Review commission: METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29673
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61242.041.17
OMON	NL-OMON29673