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

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43080

Source
ToetsingOnline

Brief title
Sinus floor augmentation with microstructured BCP granules

Condition

- Other condition

Synonym
atrophic posterior maxilla, reduced bone height of the sinus floor

Health condition

Mond- en kaakchirurgie

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Xpand Biotechnology 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, volume and bone-implant-contact area (only at 11 and

17 months) in relation to the endosseous dental implant 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 (after implant placement) 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 (buccodistal, buccomedial,

buccomesial) at 17 months after surgery.

- Pain by the Visual Analogue Scale (VAS-score) at visit 2 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 Xpand Biotechnology 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 microstructured BCP granules in inducing adequate bone quantity and quality to support endosseous dental implants in the two-staged maxillary sinus floor augmentation procedure. Secondary objective is to assess the clinical performance, functional performance (of dental implants) and pain with the use of MagnetOs micro-structured BCP granules in sinus augmentation.

Study design

This is a prospective clinical study to evaluate efficacy of micro-structured BCP granules in sinus floor augmentation. The study is designed as a small open- label, uncontrolled clinical trial.

Intervention

Patients will undergo sinus floor augmentation with Micro-structured BCP granules as bone graft substitute. 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. The Micro-structured BCP granules to be used in this study bear a CE mark and have been extensively tested in vitro and in vivo and are found to be safe and biocompatible.

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.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

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 18-70 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

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
* Psychologic instability
* 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	MagnetOs
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	17-01-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL59565.041.16