Sinus floor augmentation with microstructured BCP granules

Gepubliceerd: 12-02-2018 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29673

Bron
Nationaal Trial Register

Verkorte titel
SinusBCP

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Utrecht, Department of Oral and Maxillofacial Surgery & Special Dentistry
Overige ondersteuning: - Kuros Biosciences
- European Union’s Horizon 2020 research and innovation program (grant agreement no. 674282)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage of new bone formation in the augmented sinus floor by histomorphometrical analysis of biopsy specimens at 5 months of follow up.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

0, 5, 11, 17 months post-surgery

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-02-2018
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-02-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47531
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten