An explorative clinical prospective feasibility study to address the effectiveness and safety of calciumphosphate/poly(lactic-co-glycolic-acid) for bone augmentation in maxillary sinus floor elevation surgery

No registrations found.

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

Summary

ID

NL-OMON25916

Source
Nationaal Trial Register

Health condition

Maxillary sinus floor elevation or sinuslift
Calcium phosphate cement with poly(lactic-co-glycolic acid) or PLGA
Maxillaire sinusbodemelevatie of sinuslift
Calciumfosfaat cement met poly(lactic-co-glycolic acid) of PLGA

Sponsors and support

Primary sponsor: Radboudumc
Tandheelkunde 309, Biomaterialen
P.O. Box 9101
6500 HB Nijmegen

Source(s) of monetary or material Support: Radboudumc
Tandheelkunde 309, Biomaterialen
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CAM Bioceramics B.V.
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Intervention

Outcome measures

Primary outcome

• Assess the percentage of new bone formation by histological analysis and histomorphometry of biopsy specimens at 5 months after sinus floor elevation surgery.

• Assess implant survival at 5 months and 14 days, 11 months, 17 months and 23 months after sinus floor elevation surgery.

Secondary outcome

• Assess the bone and/or augmented bone height by radiographic evaluation at intake and further at time points 0 (directly after sinus floor elevation surgery), 5 months (at implant placement) 11 months and 23 months of follow up.

• Assess pain by using the Visual Analogue Scale (VAS-score) at all time points during follow-up.

• Assess quality of life by using the SF-36 questionnaire at all time points during follow-up.

• Assess adverse events during all follow-up visits.

Study description

Background summary

Rationale:
Various bone regenerative treatments are clinically applied to obtain sufficient bone volume for dental implant placement. Autografting, in which autologous bone is used to regenerate bone defects, is still considered the gold standard. The major disadvantage of this type of treatment is the need of an extra surgical site to harvest donor bone, leading to an extra

burden for the patient, donor site morbidity and an increased infection risk. An alternative treatment modality is the use of an allograft, in which processed cadaver bone is transplanted into the patient. Disadvantages of this type of treatment involve graft-versus-host reaction and possible transmission of diseases.

Synthetic bone substitutes are thoroughly explored in literature due to the abovementioned disadvantages related to the use of autologous bone and allografting. Synthetic calcium phosphate (CaP) ceramics are the most widely used biomaterials for bone regenerative treatments in the field of dentistry, trauma surgery, plastic and reconstructive surgery and orthopedics. Their biological performance is characterized by bioactivity and osteoconductive properties. A major drawback of CaP ceramics however, is their generally poor degradability.

Previous research provided an injectable, well-degradable porous CaP cement (CPC), successfully developed via inclusion of poly(D,L-lactic-co-glycolic acid) (PLGA) particles. The PLGA particles in CPC degrade in a relatively short time period thereby inducing porosity in CPC which increases the surface area available to interact with body fluids (Lanao et al. 2011, Lopez-Heredia et al. 2012). This process enables faster degradation of CPC, leading to the possibility of new bone formation.

An example for the importance of bone regeneration in the craniomaxillofacial region is the placement of dental implants, which requires the presence of adequate bone volume. In patients with inadequate bone volume, additional surgical techniques may be needed to achieve acceptable treatment results. In the maxilla, typically a lack of bone volume is present in the posterior region due to the presence of the often pneumatized maxillary sinus. To create enough bone quantity for the insertion of dental implants in this region, a so-called sinus floor elevation procedure can be performed. In this procedure, a small window is created in the lateral wall of the maxillary sinus, the sinus epithelium is elevated and the created space is filled with a grafting material.

In this study the effectiveness, in terms of new bone formation and implant survival, and safety of injectable CPC combined with PLGA (CPC-PLGA) will be addressed using the technique of sinus floor elevation surgery.

Objective: The primary objective is to determine the feasibility of applying CPC-PLGA in sinus floor elevation surgery in terms of bone formation and implant survival. The secondary objective is to investigate pain, health-related quality of life and the safety profile of CPC-PLGA.

Study design: Clinical prospective feasibility study.

Study population: In total, 11 male or female, 18-70 year old healthy patients that qualify for sinus floor elevation surgery, with the presence of a maxillary unilateral or bilateral

edentulous area involving the premolar and/or molar area, with a residual alveolar ridge height between 3-6 mm, will be included. A minimal amount of original bone height is needed to assure initial implant stability.

Intervention: Patients fulfilling all inclusion criteria will be requested for informed consent and scheduled for sinus floor elevation surgery with CPC-PLGA. Surgery is performed under local anesthesia. Prophylactic antibiotics will be administered 1 hour prior to the surgery and on a daily basis for seven days post-operatively. Post-surgical visits will be scheduled as in regular therapy to check the course of healing. After a healing period of 5 months, insertion of a dental implant will take place and a biopsy will be obtained via a trephine bur at the exact implant site.

Main study parameters/endpoints:

• Biopsy specimens from each patient at 5 months after sinus floor elevation surgery will be analyzed histomorphometrically on bone formation.

• Implant survival is assessed at 5, 11, 17 and 23 months after sinus floor elevation surgery.

• Pain and health related quality of life questionnaire at 7 time-points.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Sinus floor elevation procedures with autologous bone are most often performed with crista iliaca bone. Grafting procedures with bone harvested from the iliac crest cause a secondary surgical site leading to donor site morbidity and are always performed under general anesthesia. Further, this procedure increases the risk of gait disturbances, deviation in form, meralgia paresthetica (neuropraxia N. cutaneus femoralis lateralis), or herniation of intestines. Moreover, the available bone volume in the crista iliaca is limited and the grafting procedures result in prolonged operation time. The method of applying CPC-PLGA can be performed under local anesthesia because of the absent donor site, thereby significantly reducing the abovementioned drawbacks and costs.

CPC-PLGA has already extensively been tested in vitro and in vivo. No adverse biological reactions to the biomaterial have been observed. The potential risks related to this study are associated with normal sinus floor elevation surgery, such as pain, infection and loss of the grafting material.
Visits will be scheduled according to regular treatment procedures. Five months after sinus floor elevation surgery, a biopsy will be obtained during implant insertion. During visits 2 and 4 up to 9, a SF-36 questionnaire and VAS pain score will be obtained.

The Short Form (36) Health Survey (SF-36) is a patient-reported survey of patient health. The SF-36 questionnaire consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale on the assumption that each question carries equal weight. The lower the score, the more disability. The higher the score, the less disability. The eight sections are: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning and mental health.

Study objective

The primary objective is to determine the feasibility of applying CPC-PLGA in sinus floor elevation surgery in terms of bone formation and implant survival. The secondary objective is to investigate pain, health-related quality of life and the safety profile of CPC-PLGA.

Study design

• Biopsy specimens at 5 months after sinus floor elevation surgery will be analyzed histomorphometrically on bone formation. The bone area (BA) will be calculated in the region of interest which is located in the grafted area.

• Implant survival is assessed at 5, 11, 17 and 23 months after sinus floor elevation surgery, by dichotomously assessing the presence or not of the dental implant.

• Pain and health related quality of life questionnaire at 7 time-points with VAS and SF-36 questionnaires.

Intervention

Patients fulfilling all inclusion criteria will be requested for informed consent and scheduled for sinus floor elevation surgery with CPC-PLGA. Surgery is performed under local anesthesia. Prophylactic antibiotics will be administered 1 hour prior to the surgery and on a daily basis for seven days post-operatively. Post-surgical visits will be scheduled as in regular therapy to check the course of healing. After a healing period of 5 months, insertion of a dental implant will take place and a biopsy will be obtained via a trephine bur at the exact implant site.

Contacts

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Eligibility criteria

Inclusion criteria

• Healthy male or female patients aged 18-70 years

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

• Patient qualifies for sinus floor elevation surgery

• Presence of a maxillary, unilateral or bilateral, (partial) edentulous area involving the premolar and/or molar area

• Presence of a residual alveolar ridge height between 3 and 6 mm

Exclusion criteria

• Maxillary sinus pathology

• Recent extractions in the involved area

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

• Contamination of the (area around the) operative field

• Infectious diseases

• Bone metabolic disease

• Neurological disorders that could influence mental validity

• Pregnant or breast-feeding female patients

• Patients undergoing cancer therapy including immune suppression, chemotherapy and radiation

• Patients with a history of implant failure

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

• Use of bisphosphonates as a systemic drug

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-11-2016
Enrollment:	11
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-10-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42402
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5913
NTR-old	NTR6193
CCMO	NL52539.091.15
OMON	NL-OMON42402

Study results