A 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.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON42402

Source
ToetsingOnline

Brief title
A clinical feasibility study on the effectivenes and safety of CPC-PLGA.

Condition

- Bone and joint therapeutic procedures

Synonym
Alveolar resorption, shrinking of the jaw

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,CAM Bioceramics B.V., Leiden, The Netherlands

Intervention

Keyword: Bone augmentation, Calciumphosphate, PLGA, Sinus floor elevation

Outcome measures

Primary outcome

• 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.

Secondary outcome

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

Study description

Background summary

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.

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

Clinical prospective feasibility study.

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.

Study burden and risks

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.

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

- Healthy male or female patients aged 18-70 years
- 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

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2016
Enrollment:	11
Type:	Actual

Medical products/devices used

Generic name:	Calcium phosphate cement with poly(lactic-co-glycolic-acid) particles
Registration:	No

Ethics review

Approved WMO

Date:	13-10-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 25916
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL52539.091.15

Register	ID
OMON	NL-OMON25916