Onderzoek naar kaakbotophoging met kunstbot en stamcellen voor tandwortelimplantaten

No registrations found.

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

Summary

ID

NL-OMON24484

Source
Nationaal Trial Register

Brief title
STEM CELL LIFT

Health condition

human maxillary sinus; atrophic maxilla; maxillary sinus floor elevation; adipose derived mesenchymal stem cells; bone tissue engineering; bone substitute

Sponsors and support

Primary sponsor: VU University medical center, De Boelelaan 1117, 1081 HV Amsterdam
Source(s) of monetary or material Support: ZonMW, project nr. 116001009

Intervention

Outcome measures

Primary outcome

Safety: assessment of any AE or SAE related to the product and/or procedure, using patient questionnaires, physical examination, and laboratory measurements

Secondary outcome

Efficacy: Radiological/clinical assessment of bone height, bone density, and/or bone loss; dental implant integration and survival (assessment by immobility, ankylotic percussion); and histological/histomorphometrical evaluation of biopsies taken 6 months after sinus lifting

Study description

Background summary

- So far, ten patients have been uneventfully treated
- The one-step surgical procedure in clinical setting is feasible
- Safety: So far, no (serious) adverse effects have been observed during follow-up
- Efficacy of bone formation: currently being evaluated

Study objective

For patients with maxillary atrophy, the distal area of the maxilla can be augmented by transplanting bone or bone substitutes to the bottom of the maxillary sinus in order to provide sufficient alveolar bone volume for implant placement. The sinus floor elevation (or sinus lift) model is unique since it allows histological examination of biopsies obtained during the preparation for dental implant placement. In this study, the currently used autologous bone grafts and bone substitute materials will be replaced by an osteoinductive implant consisting of a calcium phosphate carrier seeded with clinically relevant quantities of minimally manipulated, freshly isolated adipose tissue stem cells in a one-step surgical procedure. This novel concept can be performed in 2 hours within the surgical theatre using a CE-marked device, thus avoiding costly GMP stem cell expansions and second intervention. We hypothesize that the thus created bioactive implant will lead to faster and improved restoration of maxillary bone volume and functionality without the drawback of complications associated with the currently used implantation materials. If successful, this offers broad potential for other bone tissue engineering applications as well.

Study design

- Open Questionnaire and Physical examination: At screening/Inclusion, Baseline (Day 0), and at 1, 6, 9, and 18 months
- Laboratory parameters (Haematology, Serum chemistry): At screening/Inclusion, Baseline (Day 0), and at 1 and 6 months
- Overall AE and SAE: all visits

Intervention

Adipose tissue aspiration followed by procurement of its stromal vascular fraction highly

enriched for adipose stem cells, and subsequent combination with synthetic bone substitutes to generate bioactive material for sinus floor elevation

Contacts

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Eligibility criteria

Inclusion criteria

- minimal bone height of 4 mm at planned implant site(s)
- no local need for horizontal bone augmentation
- healthy appearance sinus maxillaris
- smoking below 10 sigarettes a day

Exclusion criteria

- History of malignancy or chronic infectious disease (i.e. HIV, Hepatitis)
- irradiation history in jaw area
- destructive sinus surgery indicated during anamnesis
- endocarditis or heart valve abnormalities, or heart valve prostheses
- abnormalities in the immune system, or use of immune suppressants
- severe bone metabolic disorders (e.g. severe osteoporosis treated with bisphosphonates)
- Chronic use (>7 consecutive days) of anticoagulants (such as aspirin) or Non-Steroidal Anti-Inflammatory
Drugs (NSAIDS) within 15 days prior to lipoaspriation
- Signs or symptoms of infection at the time of any surgical procedure

- pregnant or nursing, or intention to become pregnant

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-05-2010
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-02-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35169
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4272
NTR-old	NTR4408
CCMO	NL29581.000.09
OMON	NL-OMON35169

Study results