Onderzoek naar kaakbotophoging met kunstbot en stamcellen voor tandwortelimplantaten

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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...

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

Samenvatting

ID

NL-OMON24484

Bron
NTR

Verkorte titel
STEM CELL LIFT

Aandoening

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

Ondersteuning

Primaire sponsor: VU University medical center, De Boelelaan 1117, 1081 HV Amsterdam
Overige ondersteuning: ZonMW, project nr. 116001009

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

- 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

Doel van het onderzoek

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.

Onderzoeksopzet

- 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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	31-05-2010
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-02-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35169
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten