A clinical feasibility study to evaluate the effectiviness and safety of VivescOs TM as bone graft for reconstruction of intra-oral osseous defects.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24005

Source
NTR

Brief title
N/A

Health condition

Intra-oral defects, due to loss of teeth/molars after trauma or extraction, were reconstructed with VivescOs.

Sponsors and support

Primary sponsor: Isotis, Bilthoven, the Netherlands

Intervention

Outcome measures

Primary outcome

Safety of VivescOs has been confirmed.

Secondary outcome

Efficacy of VivescOs is doubted.

Study description

Background summary

To investigate the power of Bone Tissue Engineering, 10 patients with various intra-oral osseous defects were selected. After a bone marrow aspirate was taken, stem cells were cultured, expanded and grown for 7 days on a bone substitute in an osteogenic culture medium to allow formation of a layer of extracellular bone matrix. At the end of the procedure, this ?living bone substitute? was not only re-implanted in the patient, but simultaneously subcutaneously implanted in mice to prove its osteogenic potency.

In 7 patients, a viable ?living bone substitute? was successfully constructed, which was proven by bone formation after subcutaneous implantation in mice (ectopic bone formation). However, the same construct generally failed to form bone in the patient?s intra-oral osseous defects (orthotopic bone formation). Although biopsies, taken 4 months after reconstructing the intra-oral bone defect, showed bone formation in 3 patients, in only 1 patient bone formation was convincingly induced by the tissue engineered construct.

Although a bone substitute covered by osteogenic cells and extracellular bone matrix is capable of producing bone in a non-bone environment in mice, the same construct has hardly any potency to produce bone in an osseous defect in humans in the current clinical setting.

Study objective

Cultured mesenchymal stem cells differentiated into osteoblasts and seeded on scaffolds can induce bone formation.

Study design

N/A

Intervention

"VisvescOs" and "tissue engineered bone".

"Preoperatively, 4 weeks before the
implantation procedure, a aspiration biopsy will be taken.

Post-operatively patients will be evaluated using radiographic analysis by OphtoPantomoGrams (OPG), histological analysis by biopsy specimens and clinical evaluation of functionality, 3 months, 6 months, 9 months, 12 months and 15 months after surgery.

Contacts

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Eligibility criteria

Inclusion criteria

Repair of the intra-oral defect was indicated as preparation for dental implant placement in a secondary stage.

Exclusion criteria

1. Presence of local or systemic disease;

2. Pregnancy, cancertherapy;

3. Previous participation in another trial within 30 days;

4. Known hypersensitivity for penicillin, streptomycin.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2000
Enrollment:	10
Type:	Actual

Ethics review

Positive opinion

Date:	26-05-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL653
NTR-old	NTR714
Other	: N/A
ISRCTN	ISRCTN92152389

Study results

Summary results
N/A