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

Submission date 26/09/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 26/09/2006	**Overall study status** Completed	
Last Edited 10/03/2008	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Clinical feasability study

Primary study design
Interventional

Secondary study design
Other

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Intra-oral bone defects, loss of teeth/molars

Interventions
VivescOs™ versus tissue engineered bone.

Preoperatively, four 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 at three months, six months, nine months, 12 months and 15 months after surgery.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
VivescOs™

Primary outcome measure
Safety of VivescOs™ has been confirmed.

Secondary outcome measures
Efficacy of VivescOs™ is doubted.

Overall study start date
08/11/2000

Completion date
21/01/2003

Eligibility

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

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
10

Key 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.

Date of first enrolment
08/11/2000

Date of final enrolment
21/01/2003

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht (UMCU)
Utrecht
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3584 CX

Sponsor information

Organisation
IsoTis NV (The Netherlands)

Sponsor details
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Sponsor type
Industry

ROR
https://ror.org/04qce9v53

Funder(s)

Funder type
Industry

Funder Name
IsoTis NV (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration