

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
Registration date 26/09/2006	Overall study status Completed	☐ Protocol
Last Edited 10/03/2008	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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 feasibility study

Primary study design

Interventional

Study type(s)

Treatment

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(s)

Safety of VivescOs™ has been confirmed.

Key secondary outcome(s))

Efficacy of VivescOs™ is doubted.

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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

Netherlands

3584 CX

Sponsor information

Organisation

IsoTis NV (The Netherlands)

ROR

<https://ror.org/04qce9v53>

Funder(s)**Funder type**

Industry

Funder Name

IsoTis NV (The Netherlands)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration