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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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
Netherlands
3584 CX

Sponsor information

Organisation

IsoTis NV (The Netherlands)

Sponsor details

Prof. Bronkhorstlaan 10-D Bilthoven Netherlands 3723 MB

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 summaryNot provided at time of registration