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The assessment of the success of implants in the maxillary sinus graft

Submission date	Recruitment status	[ ] Prospectively registered
20/10/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/10/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/10/2008	Oral Health	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1042

Study information

Scientific Title

Study objectives
This study aimed at analysing the success of maxillary sinus graft using biomaterial (demineralised bovine bone graft) and platelets-rich plasma. Bone neoformation and implant success rate were recorded.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics approval was sought as this trial used only routine procedures, and informed consent was obtained from all participants.

Study design
Interventional single-arm trial

Primary study design
Interventional

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Grafts for severely reabsorbed edges of the maxillary sinus after tooth extraction

Interventions
All participants received maxillary sinus graft using biomaterial (demineralised bovine bone graft) and platelets-rich plasma. The implant was evaluated at 6 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following were assessed at 6 months:
1. Implant failure rate
2. Success rate of implants
3. Graft bone formation rate

Secondary outcome measures
The following were assessed at 6 months:
1. Bone density (subjective), defined during the surgery - D3
2. Sub-antral rating as measured by three-dimensional imaging or radiography - SA1

Overall study start date
01/09/2006

Completion date
29/02/2008

Eligibility

Key inclusion criteria
1. Both males and females, no age limits
2. Patients who were admitted to the Centre for Post-Graduate Studies, Dental Center CLIVO, Rio de Janeiro (AORJ, FAISA/ CIODONTO), who needed graft in the maxillary sinus for the insertion of implants and subsequent construction of the prosthesis

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
30

Key exclusion criteria
Cases in which, at the time of surgery, membrane was pierced greater than 2 mm, resulting in the abortion procedure.

Date of first enrolment
01/09/2006

Date of final enrolment
29/02/2008

Locations

Countries of recruitment
Brazil

Study participating centre

Street benjamin constant 61 s 803
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Sponsor information

Organisation
Dental Center CLIVO (Centro Livre de Odontologia) (Brazil)

Sponsor details
Rio de Janeiro College of Dentistry (AORJ)
RUA Barão do Flamengo
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Sponsor type
Hospital/treatment centre

Website
http://www.clivo.com.br

Funder(s)

Funder type
University/education

Funder Name
Dental Center CLIVO (Centro Livre de Odontologia), Rio de Janeiro College of Dentistry (AORJ, FAISA/CIODONTO) (Brazil)

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