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

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

The following were assessed at 6 months:

- 1. Implant failure rate
- 2. Success rate of implants
- 3. Graft bone formation rate

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

Rio de janeiro Brazil 20241150

Sponsor information

Organisation

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration