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Partial bone reconstruction of alveolar rims for implant placement

Submission date
16/06/2017

Recruitment status
No longer recruiting

Registration date
28/06/2017

Overall study status
Completed

Last Edited
12/12/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The adult population of the city of Córdoba in Argentina currently has a high amounts of people who require dental extractions (teeth pulling), leading to issues with function and the looks. In the posterior sector (back section) of the upper jaw, bone remodeling following dental extractions leads to an unfavorable situation for rehabilitating with the implants that meet the basic biomechanical standards to support the corresponding prosthesis. Usually, when bone remodeling (saving) is done after a dental extraction, this makes it more difficult to put in a dental implant (an artificial tooth) and have the implant be successful. One of the strategies commonly used in surgical practice to add bone to the jaw is called a maxillary sinus floor elevation. This procedure adds a graft (which means placing tissue from one area of a body to another). Grafts can be autologous (tissue from the same individual) or allogeneic (tissue from someone else) but they need to be able to create enough bone height in the jaw in order to place implants. The grafts must comply with certain requirements in order to regenerate new bone and fix the bone to the jaw. One type of graft that is commonly used is Lyophilized Human Bone (LHB). The aim of this study is to evaluate, through clinical examination and imaging, the efficacy of using LHB as graft in maxillary sinus floor elevation.

Who can participate?
Adults aged 18 to 65 who have a tooth loss.

What does the study involve?
Participants attend a study visit where they undergo screening tests. They then undergo the maxillary sinus floor elevation. The materials used as a graft is LHB and contains of bone from the Blood Bank of the National University of Cordoba. Participants attend follow up appointments at day seven and day 180 after their procedure in order to assess the success of the bone regeneration and the dental implant.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
Faculty of Dentistry - National University of Cordoba (Argentina)

When is the study starting and how long is it expected to run for?
February 2014 to February 2016

Who is funding the study?
Department of Science and Technology, Ciudad University (Argentina)

Who is the main contact?
Dr Ricardo Bachur

Study website
http://www.odo.unc.edu.ar/268-cieis-y-cais/1336-evaluacion-registro-y-fiscalizacion-de-las-investigaciones-en-salud

Contact information

Type(s)
Scientific

Contact name
Dr Ricardo Bachur

ORCID ID
http://orcid.org/0000-0002-2260-3107

Contact details
Cátedra de Cirugía III
Facultad de Odontología
Universidad Nacional de Cordoba
Haya de la Torre S/N
Ciudad universitaria
Córdoba
Argentina
5000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ODO67

Study information

Scientific Title

Non autologous human bone in adult patients to increment of mandible and maxillary bone for success of dental implant

Study objectives
The aim of this study is evaluate, through clinical studies and image diagnosis, the efficacy of human non-autologous bone as an alternative in the surgery of partial reconstruction of alveolar rims in jaw and maxilla for collocating dental implants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research and Ethics Committee of the Ministry of Health of the Province of Cordoba (Facultad Odontología-Universidad Nacional Córdoba), 12/08/2014, ref: ODO67

Study design
Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files (in Spanish)

Health condition(s) or problem(s) studied
Bone loss in mandibule and maxilla

Interventions
Participants attend a first visit where they provide their clinical history and have the state of their oral cavity recorded. They undergo laboratory tests, x-rays and CT scans. Participants then undergo the surgery in order to recover the bone and have the maxillary sinus floor elevation. The material used as a graft in the surgery is LHB and irradiated, composed of ground bone particles ranging from 0.2 to 1 mm in size from the Blood Bank of the National University of Córdoba.

Participants attend follow up appointments at day seven and 180 where they undergo clinical examination and imaging to assess bone regeneration and the success of the dental implant.

Intervention Type
Procedure/Surgery

Primary outcome measure
Bone regeneration is measured in millimeters using digital orthopantomographs by a specialist using the standard technique for orthopantomography, model Planmeca Autoprint, PM 2002, with automatic processor Kodak XP 400 at baseline, day seven and day 180.

Secondary outcome measures
Success of dental implant collocation is assessed by no-mobility of the implant when loaded at baseline, day seven and day 180.

Overall study start date
21/02/2014

Completion date
28/02/2016

Eligibility

Key inclusion criteria
1. Patients of both sexes
2. Aged from 18 to 65 years old
2. Experience of single or multiple tooth loss whose residual alveolar ridges are atrophic and therefore insufficient for an appropriate rehabilitation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15

Key exclusion criteria
1. History of type 1 diabetes mellitus
2. Symptomatic hypo- or hyperthyroidism
3. Immunodeficiency problems
4. Sinusitis
5. Chemotherapy and/or radiotherapy
6. Arterial hypertension above 159/94
7. In the 6-month window period after acute myocardial infarction or cerebrovascular accident
8. Chronic periodontal disease
9. Bone diseases such as osteomalacia
10. Arthritis
11. Infections

12. Rheumatism or osteoporosis
13. Cirrhosis
14. Consumers of osteoactive drugs such as bisphosphonates, denosumab, raloxifene, teriparatide or corticoids
15. Pregnant

Date of first enrolment
01/04/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Argentina

Study participating centre
Faculty of Dentistry National University of Cordoba (Facultad de Odontología Universidad Nacional de Córdoba)
Haya de la Torre s/n
Ciudad Universitaria
Pabellón Argentina
Córdoba
Argentina
5000

Sponsor information

Organisation
Department of Science and Technology (Secretaría de Ciencia y Técnica)

Sponsor details
Juan Filloy s/n
Ciudad University
Córdoba
Argentina
5000

Sponsor type
University/education

Website
https://www.unc.edu.ar/ciencia-y-tecnolog%C3%ADa/contactos-secyt

ROR
https://ror.org/006j36p28

Funder(s)

Funder type
Not defined

Funder Name
Department of Science and Technology, Ciudad University

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Ricardo Bachur Chair of Surgery at ricardo.bachur@unc.edu.ar

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/03/2019	12/12/2019	Yes	No