

Partial bone reconstruction of alveolar rims for implant placement

Submission date 16/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 12/12/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bone loss in mandible 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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Sponsor information

Organisation

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

ROR

<https://ror.org/006j36p28>

Funder(s)

Funder type

Not defined

Funder Name

Department of Science and Technology, Ciudad University

Results and Publications

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes