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Reconstructive surgical therapy of peri-implantitis bone defects

Submission date
20/05/2019

Recruitment status
No longer recruiting

Registration date
03/06/2019

Overall study status
Completed

Last Edited
17/03/2023

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Periimplantitis is a pathological condition that occurs in the tissues surrounding dental implants. It is characterized by inflammation of the peri-implant connective tissue and loss of progressive support bone. In a recent systematic review, a 22% prevalence of peri-implantitis has been described. If the literature is analyzed, it can be verified how different percentages of prevalence are reported due to the different definition of this pathological condition depending on the study analyzed, being from 1% to 47%. In addition, it has been suggested that this bone loss is time-dependent and that the follow-up time of the different studies can also affect the percentage of prevalence described. The potential benefit of using bone substitutes / biological agents in reconstructive procedures for the treatment of periimplantitis remains undefined for the time being due to the existence of few clinical studies with very heterogeneous designs and different follow-up times. Concerning the material that should be used during the reconstructive procedure, the existing literature is heterogeneous. Several studies evaluate the effectiveness of material without comparing with any control group, while others either compare the use of a material with the performance of only mechanical debridement or with the use of a different material. For this reason, it is difficult to draw solid conclusions about the ideal material.

Who can participate?
1. Age ≥ 18 years
2. Peri-implant bone defect ≥ 3mm assessed radiographically
3. PPD ≥ 5mm combined with bleeding on probing or supuration
4. Intra-surgically, bone defect must have at least a intraosseous component of 3mm and a width of no more than 4mm
5. implants ≥ 1 year in function

What does the study involve?
The test group will be treated with xenograft cover with a resorbable collagen membrane and the control group will be treated with xenograft only.

What are the possible benefits and risks of participating?
The benefit is the reconstruction of the peri-implant bone previously lost and arrest the peri-

implant pathology.
The risk is not being able to stop the disease.

Where is the study run from?
1. Periocentrum Bilbao. Bilbao. 48008. Spain.
2. Periodontology postgraduate program at the University of Basque Country Lejona, 48940 Spain.

When is the study starting and how long is it expected to run for?
February 2019 to February 2022

Who is funding the study?
Periocentrum Bilbao.

Who is the main contact?
Erik Regidor
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019012

Study information

Scientific Title
Reconstructive surgical therapy of peri-implantitis-related bone defects: Application of a bovine-derived bone xenograft with or without a resorbable collagen membrane. Multicenter controlled randomized clinical trial

Acronym
RPT

Study objectives
The use of a resorbable membrane in combination with a xenograft of bovine origin offers an additional benefit in the treatment of peri-implant bone defects compared to the use of the xenograft alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/04/2019, Ethical Committee of the Basque Country (CEIm de Euskadi [Comité de Ética de la Investigación Clínica con medicamentos] Farmaziako Zuzendaritza / Dirección de Farmacia. Osasun saila / Departamento de Salud. Eusko Jaurlaritza / Gobierno Vasco C/ Donostia-San Sebastián, 1 – 01010 Vitoria-Gasteiz; ceic.eeaa@euskadi.eus; 945 01 64 59; http://www.euskadi.eus/comite-etico-investigacion-clinica/), ref: PS2019012.

Study design
Multicenter randomized controlled clinical trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Intraosseous peri-implant defects

Interventions
The test group will be treated with xenograft cover with a resorbable collagen membrane.

Control group will be treated with xenograft only.

The intervention will we realized in a single session and the follow-up will be 12 months after the surgical procedure. Randomization will be carried out by means of 5 blocks by a sequence generated by the computer.

Intervention Type
Procedure/Surgery

Primary outcome measure
Probing depth (PS) is measured in 6 locations per implant. It consists of probing from the margin of the peri-implant mucosa to the most apical part of the peri-implant defect at baseline, at 6 months and at 12 months.

Secondary outcome measures
1. Filling of the radiographic defect is measured using intraoral radiographs of the implant at baseline, 6 months and 12 months. The defect that is appreciated in the initial radiography with the filling in the following ones will be compared.
2. Mucosal recession is measured at one vestibular point of each implant. Measured from the apical margin of the implant-supported restoration to the margin of the peri-implant mucosa at baseline, at 6 months and at 12 months.
3. Bleeding on probing is measured in 6 locations per implant in basal at 6 months and 12 months.
4. Plaque control is measured in 6 locations per implant in basal at 6 months and 12 months.
5. Presence of complications is measured using membrane exposure at healing period. It will be checked if there is primary closure of the lesion or if there is membrane exposure.
6. Intervention time. Is measured by a chronometer since the first incision until the last suture.
7. Patient satisfaction and morbidity are measured using a visual analogic scale at 2 weeks, 6 months and 12 months to know the postoperative morbidity and perception and satisfaction with the procedure.
8. Volumetric changes are measured using an intraoral scanner and a digital computer program that superimposes an initial scanner with the posterior ones to see the volumetric changes at baseline, at 6 months and 12 months.

Overall study start date
01/02/2019

Completion date
28/02/2022

Eligibility

Key inclusion criteria
1. Show radiographically peri-implant intraosseous defects of at least 3mm depth.
2. Depth of clinical probing ≥ 5mm with bleeding and/or suppuration.
3. Intra-surgically, the infra-osseous defect must have at least one intraosseous component of 3mm and a width of no more than 4mm.
4. The implant to be treated must have been in function for at least 12 months.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40 patients divided in two groups being 20 patients per group

Total final enrolment
43

Key exclusion criteria
1. Has diabetes mellitus, hyperparathyroidism and/or osteomalacia.
2. Treated with corticosteroids.
3. Medicated with drugs that induce gingival hyperplasia.
4. Allergic to penicillin or who have taken antibiotics in the last 6 months.
5. Pregnant or breast-feeding patients.
6. Patients with osteoporosis.
7. Impossibility of stabilizing bovine bone with collagen or primary closure of soft tissue.
8. Patients with collagen allergy.
9. Patients treated with radiotherapy.

Date of first enrolment
01/07/2019

Date of final enrolment
28/01/2021

Locations

Countries of recruitment
Spain

Study participating centre
PerioCentrum Bilbao
Alameda Urquijo street 2, 7th floor
Bilbao
Spain
48008

Study participating centre
University of basque country
Sarriena Borough

Lejona
Spain
48920

Sponsor information

Organisation
Periocentrum Bilbao

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Sponsor type
Research organisation

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Periocentrum Bilbao

Results and Publications

Publication and dissemination plan
When we reach the total number of patients treated we will follow them for 12 months. After we will prepare the manuscript and publish it before finishing 2021 in a high impact journal.

Intention to publish date
01/10/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		03/06/2019	04/06/2019	No	No
Results article		19/02/2023	17/03/2023	Yes	No