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Treatment of peri-implantitis with allografts and enamel proteins

Submission date 19/12/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 21/12/2023	**Overall study status** Ongoing	
Last Edited 03/03/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Peri-implantitis is a condition that occurs in the tissues surrounding dental implants. It is characterized by inflammation of the connective tissue around the implant and loss of support bone. Allografts (transplanted tissues) have been described as a good option to reconstruct the bone defect related to peri-implantitis. Enamel matrix proteins have been previously described as an ideal material for periodontal regeneration alone or in combination with bone grafts. This study aims to measure the potential benefit of adding enamel matrix proteins to allografts in the reconstruction of bone defects due to peri-implantitis progression.

Who can participate?
Patients aged 18 years and over with implants for 1 year or more and diagnosed with advanced peri-implantitis

What does the study involve?
Participants will be randomly allocated to the test or control group during surgery. The control group will be treated with allografts alone. The test group will be treated with enamel matrix proteins and allografts. Sutures will be removed at 2 weeks after surgery. Clinical examinations will be performed at 4, 12, 24 and 48 weeks after surgery. Maintenance therapy will be carried out at 12, 24 and 48 weeks after therapy.

What are the possible benefits and risks of participating?
The benefit would be that participants' peri-implant disease will be treated and arrested. There is no additional risk of participating.

Where is the study run from?
Clínica Ortiz-Vigón (Spain)

When is the study starting and how long is it expected to run for?
September 2023 to August 2026

Who is funding the study?
Arrow Development SL (Spain)

Who is the main contact?
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Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PS2023069

Study information

Scientific Title
Influence of enamel matrix derivatives for the treatment of peri-implant-related osseous defects with minimal flap approach: a randomized clinical trial

Study objectives
The enamel matrix derivate simultaneous to intra-bony peri-implant related defect reconstruction with allogeneic bone graft has a better outcome in terms of radiographic defect fill and re-establishing peri-implant health when comparing with using only an allogeneic bone graft with minimally invasive surgical approaches.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/12/2023, Basque Country local ethics committee (C/ Donostia-San Sebastián, nº 1. Vitoria-Gasteiz 01010, Vitoria, 01010, Spain; +34 (0)945 01 92 96; ceic.eeaa@euskadi.eus), ref: PS2023*

Study design
Randomized clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peri-implantitis

Interventions
Study participants will be randomly allocated to the test or control group during surgery, just after completing implant decontamination procedures. The randomization sequence is determined using a block size of 4 with a 1:1 allocation. Allocation will be concealed through the use of sealed, opaque envelopes. Outcome assessors and patients will be blinded to group allocation.

Surgical procedures will be performed 1 month after non-surgical periodontal treatment. On the same day of surgical therapy, an antibiotic will be administered for 7 days (amoxicillin 500 mg / 7 days / 8 hours). First, a minimally invasive surgical flap will be prepared over the implant neck. Large flaps will be avoided to minimize surgical post-operative complications such as dehiscence and loss of biomaterial.

Control group: surgical reconstructive treatment of periimplantitis by means of implant surface decontamination with mechanical methods (Labrida BioClean Brush®), and osseous defect reconstruction by means of allogeneic bone graft (Straumann Allograft in particles).

Test group: surgical reconstructive treatment of periimplantitis by means of implant surface decontamination with mechanical methods (Labrida BioClean Brush®), and osseous defect reconstruction by means of allogeneic bone graft (Straumann Allograft in particles) and adjunctive enamel matrix proteins (Straumann Emdogain®).

Sutures will be removed 2 weeks after surgical therapy. Clinical examinations will be performed at 4,12,24 and 48 weeks after surgical therapy. Maintenance therapy will be realized at 12, 24 and 48 weeks after therapy.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Treatment success will be defined as the absence of bleeding on probing (BoP)/pus, probing pocket depth (PPD) ≤5 mm and ≤1 mm recession (measured using Periodontal Manual probe CP 15 Hu-Friedy) at 4, 12, 24 and 48 weeks after surgical therapy

Key secondary outcome(s))
Clinical assessments:
One calibrated examiner will perform the assessments. The following variables will be assessed at four sites around the implant: plaque, probing pocket depth (PPD), bleeding on probing (BoP), probing attachment level (PAL) recession (REC). Keratinized mucosa (KM) will be measured in the buccal aspect of each included implant using Periodontal Manual probe CP 15 Hu-Friedy at baseline, 24 and 48 weeks.

Surgical assessments:
Defect configuration will be measured by one calibrated examiner in each clinical center to understand how much impact it has on clinical outcomes, measured using Periodontal Manual probe CP 15 Hu-Friedy intra-surgically. Osseous defect-related measures / recording of osseous defect characteristics:
1. Defect width (measured in mesial, distal, buccal, and palatal/lingual aspects)
2. Distance from implant neck to depth of the osseous defect (measured in mesial, distal, buccal, and palatal/lingual aspects)
3. Distance from osseous ridge to depth of the osseous defect (measured in mesial, distal, buccal, and palatal/lingual aspects)

Radiographic assessments:
Radiographic marginal bone level. Each included implant will be measured in mesial and distal aspects in mm with Image-J® digital software using intra-oral radiographs obtained before surgery (baseline) and at 6- and 12-month re-examinations. Analysis of radiographs will be performed by a specialist. The examiner will be blinded to treatment procedures. The assessment will include defect fill in both follow-up visits.

Volumetric changes:
Linear changes measured in Implant-Studio® digital software in 1, 3 and 5 mm from the mucosal peri-implant margin. Intra-oral scanning will be obtained before surgery (baseline) at 6 months and 12 months of re-examination. Analysis of STL archives will be performed by a specialist. The examiner will be blinded to treatment procedures. The assessment will include volumetric changes after matching the baseline intra-oral scanning, 6 months of intra-oral scanning and 12 months of intra-oral scanning.

Completion date
01/08/2026

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Peri-implant bone defect ≥3 mm assessed radiographically
3. PPD ≥5 mm combined with bleeding on probing or suppuration
4. Intra-surgically, bone defect must have at least an intraosseous component of 3 mm and a width of no more than 4 mm
5. Implants ≥1 year in function

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Treated for peri-implantitis during the previous 6 months
2. Intake of systemic or local antibiotics during the previous 6 months
3. Pregnant patients
4. Systemically unhealthy patients
5. Patients allergic to collagen

Date of first enrolment
01/01/2024

Date of final enrolment
26/02/2025

Locations

Countries of recruitment
Spain

Study participating centre

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Sponsor information

Organisation
Arrow Development S.L.

Funder(s)

Funder type
Research organisation

Funder Name
Arrow Development S.L.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. All the information and documents will be saved in a secure database under a highly secure password and will be supervised by the study monitor.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			19/12/2023	No	No