ISRCTN18159776 https://doi.org/10.1186/ISRCTN18159776

Treatment of peri-implant diseases with enamel matrix proteins

Submission date	Recruitment status	[_] Prospectively registered
08/03/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/04/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/03/2025	Surgery	

Plain English summary of protocol

Background and study aims
Periimplantitis is a condition that occurs in the tissues surrounding dental implants. It involves inflammation of the connective tissue around the implant and support bone loss. The objective of the treatment of peri-implantitis is to resolve the inflammation of the soft tissues and stop the additional loss of the support bone. Non-surgical treatment is not enough to stop the disease, while surgical treatment has shown greater effectiveness. The goal of reconstructive procedures for peri-implant bone defects is to restore the implant support tissues and improve aesthetics and bone integration. The aim of this study is to evaluate the effectiveness of enamel matrix derivate with a bovine (cow) bone graft and a resorbable membrane in the treatment of peri-implant bone defects.

Who can participate?
Patients aged 18 and over with advanced peri-implantitis at one or more implants

What does the study involve?
Participants are randomly allocated to the test surgery with the enamel matrix derivative or the control surgery without the enamel matrix derivative. Clinical examinations are performed at 4, 12, 24 and 48 weeks after surgery.

What are the possible benefits and risks of participating?
The possible benefits of participating are treatment for peri-implantitis and improved prognosis for dental implants. There is no additional risk of participating because it is a treatment that eliminates the infection around the implants.

Where is the study run from?
Periocentrum Bilbao (Spain)

When is the study starting and how long is it expected to run for?
February 2021 to February 2024

Who is funding the study?
1. Straumann (Switzerland)
2. Arrow Research Development SL

Who is the main contact?
1. 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
Nil known

Study information

Scientific Title
Application of enamel matrix derivate, deproteinized bovine bone and collagen membrane for the reconstructive treatment of periimplant intrabony defect: a randomized clinical trial

Study objectives
The enamel matrix derivate simultaneous to guided bone regeneration with xenograft and collagen membrane has a better outcome in terms of radiographic defect fill and re-establishing peri-implant health compared with when only xenograft and collagen membrane is used.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/03/2021, 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; +34 (0)945 01 64 59; ceic.eeaa@euskadi.eus), ref: PS2021008

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Interventions
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). Full-thickness flap will be elevated and infected tissues will be removed. Implant surface mechanical decontamination (Labrida BioClean®) will be performed but the surface roughness will not be modified or reduced. The randomly assigned treatment will be revealed after this step.

Test procedure: First EDTA (Ethylenediaminetetraacetic acid) will be applied to the implant surface for 2 minutes. Then the site will be carefully rinsed with sterile saline and Emdogain will be applied to the implant surface and adjacent teeth. The intrabony defect will be filled with Straumann Xenoflex® and Straumann MembraneFlex® resorbable membrane and the flaps will be sutured to their previous position.

Control procedure: The intrabony defect will be filled with Straumann Xenoflex® and Straumann MembraneFlex® resorbable membrane and the flaps will be sutured to their previous position. 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 measure
Probing depth (PS) in six locations per implant, measured by probing from the margin of the peri-implant mucosa to the most apical part of the peri-implant defect with a manual periodontal probe at baseline and at 6 and 12 months

Secondary outcome measures
1. Filling of the radiographic defect measured using intraoral radiographs of the implant at baseline, 6 months and 12 months
2. Mucosal recession measured at one vestibular point of each implant from the apical margin of the implant-supported restoration to the margin of the peri-implant mucosa with a manual periodontal probe at baseline, at 6 months and at 12 months
3. Bleeding on probing measured with a manual periodontal probe in six locations per implant in basal at 6 months and 12 months
4. Plaque control measured with a manual periodontal probe in six locations per implant in basal at 6 months and 12 months
5. Patient satisfaction and morbidity measured using a visual analogue scale (VAS) at 2 weeks, 6 months and 12 months
6. Volumetric changes measured using an intraoral scanner and a digital computer program at baseline, at 6 months and 12 months

Overall study start date
01/02/2021

Completion date
28/02/2024

Eligibility

Key inclusion criteria
1. Patients that show radiographically peri-implant intraosseous defects of at least 3 mm depth
2. Depth of clinical probing ≥5 mm with bleeding and/or suppuration
3. Intra-surgically, the infra-osseous defect must have at least one intraosseous component of 3 mm and a width of no more than 4 mm
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 into two groups (20 patients per group)

Total final enrolment
40

Key exclusion criteria
1. Patients with diabetes mellitus, hyperparathyroidism and/or osteomalacia
2. Patients treated with corticosteroids
3. Patients medicated with drugs that induce gingival hyperplasia
4. Allergic to penicillin or who have taken antibiotics in the last 6 months
5. Pregnant or breastfeeding 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
01/04/2021

Date of final enrolment
02/02/2023

Locations

Countries of recruitment
Spain

Study participating centre
Periocentrum Bilbao
Alameda Urquijo Street 2, 7th floor
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Sponsor information

Organisation
ThinkingPerio Research

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Sponsor type
Hospital/treatment centre

Website
https://periocentrum.com/

Funder(s)

Funder type
Industry

Funder Name
Straumann

Funder Name
Arrow Research Development SL

Results and Publications

Publication and dissemination plan
When the researchers reach the total number of patients treated they will follow them for 12 months. After they will prepare the manuscript and publish it before the end of 2024 in a high-impact journal.

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Erik Regidor (erik@ortizvigon.com) and Alberto Ortiz-Vigón (alberto@ortizvigon.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			15/04/2021	No	No
Results article		26/03/2025	27/03/2025	Yes	No