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Dental implant surface cleaning with hydrogen bubbles

Submission date 02/01/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/01/2023	**Overall study status** Ongoing	
Last Edited 06/03/2024	**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 tissue and loss of the supporting bone. The objective of the treatment of peri-implantitis is to resolve the inflammation of the soft tissues and stop the additional loss of the supporting bone. Non-surgical treatment is not enough to stop the disease, and surgical treatment has shown greater effectiveness and in the longer term. Factors such as the implant surface decontamination method have a significant influence on the results of surgical treatment. Several implant surface decontamination methods have been proposed but none of them has been shown to be better than the others. Decontamination methods should not only effectively remove the attached biofilm (bacteria) and calculus (hardened plaque), but also avoid any significant negative changes at the implant surface in order to
perform the reconstructive surgery around the implant surface and promote the re-osseointegration (bone ingrowth into the implant).
The aim of this study is to evaluate the clinical effectiveness of the new implant surface decontamination method Galvosurge® in the treatment of peri-implant bone defects.

Who can participate?
Systemically healthy patients aged 18 years and over with advanced peri-implantitis at one or more implants

What does the study involve?
Surgery procedures will be performed 1 month after non-surgical periodontal treatment. Infected tissues will be removed and implant surface decontamination will be performed with either Galvosurge® or a control method (titanium brush). The bone defect will be filled 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 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 of participating is the treatment of the peri-implant pathology and improved implant prognosis. 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 2022 to December 2025

Who is funding the study?
Arrow Development S.L. (Spain)

Who is the main contact?
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Contact information

Type(s)
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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
Influence of new implant surface decontamination method (Galvosurge®) in the surgical reconstructive treatment of peri-implant related intrabony defects

Study objectives
The Galvosurge implant surface decontamination method has a better outcome in terms of the effective removal of the attached biofilm and calculus from the implant surface when compared with the titanium brush method.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/12/2022, Comité De Ética De La Investigación Con Medicamentos De Euskadi (CEIm-E; Postal address: C/ Donostia-San Sebastián, nº 1. Vitoria-Gasteiz 01010, Spain; +34 (0)945 015 634; ceic.eeaa@euskadi.eus), ref: PS2022077

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Removal of the attached biofilm and calculus from dental implant surface

Interventions

Surgical procedures will be performed one month after non-surgical periodontal treatment. On the same day of surgical therapy an antibiotic will be administered for 7 days (amoxicillin 500mg /7 days/8 hours). Full thickness flap will be elevated and infected tissues will be removed.

Implant surface decontamination will be performed with test (Galvosurge®) or control methods (titanium brush) randomly assigned. Randomization will be performed using a Microsoft Excel®-generated randomization list, with the treatment allocation contained in sealed envelopes that will be prepared by a research assistant not involved as clinician or examiner. Both the patient and the clinician performing the surgical intervention will be masked to the group allocation until the randomization envelope will be opened intra-surgically. The examiner will be masked to the group allocation at all follow-up visits, and the patients will be asked not to reveal their treatment assignment to the examiners.

The intrabony defect will be filled with Xenogain Collagen® and Xenoprotect® 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
A composite definition of successful treatment outcome defined as the absence of bleeding or suppuration on probing, absence of peri-implant probing depth ≤5 mm and mucosal recession ≤1 mm at 4, 12, 24 and 48 weeks. 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

Secondary outcome measures
Measured at 4, 12, 24 and 48 weeks:
1. Radiographic filling of the defect will be measured with Image J Software
2. Risk of appearance of complications measured with a questionnaire recording suppuration, membrane exposure or grafting material exposure and soft tissue dehiscence.
3. Patient-reported outcomes measurements: patient pain perception and general satisfaction with surgical procedure and final outcomes.
4. Need for analgesia after surgery measured using patient records
5. Intervention time measured using patient records
6. Soft and hard tissue volumetric changes measured with an intraoral scanner and compared with implant planning software
7. Impact of defect configuration in treatment outcomes; taking into account the presence or absence of buccal bony wall and the number of bony walls the researchers will perform a further analysis of the impact of these defects in the final reconstructive outcomes

Overall study start date
30/09/2022

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Peri-implant bone defect ≥3 mm assessed radiographically
3. Peri-implant pocket depth (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 4mm
5. Implants ≥1 year in function

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
40

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
01/02/2023

Date of final enrolment
01/09/2024

Locations

Countries of recruitment
Spain

Study participating centre
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Arrow Development S.L.

Results and Publications

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

Intention to publish date
01/01/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			04/01/2023	No	No