

# Dental implant surface cleaning with hydrogen bubbles

<b>Submission date</b> 02/01/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/01/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/10/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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® as adjunctive to titanium brush in the decontamination of implant surface and treatment of peri-implant bone defects comparing with titanium brush alone.

### 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?

Dr Erik Regidor Correa

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## Contact information

### Type(s)

Principal investigator

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# Additional identifiers

## 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

Current study objectives:

The Galvosurge implant surface decontamination method as adjunctive method to titanium brush 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 alone.

Previous 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)

1. 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
2. Approved 27/12/2022, local ethics committee of Basque Country (BioCruces, Plaza del Hospital s/n, 48903 Barakaldo, Bilbao (Bizkaia), Bilbao, 48903, Spain; +34 (0)945 01 80 00; ceic.eeaa@euskadi.eus), ref: PS2022077

### Study design

Interventional randomized controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Removal of the attached biofilm and calculus from dental implant surface

### Interventions

Current interventions as of 06/10/2025:

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 500 mg /7 days/8 hours). Full thickness flap will be elevated and infected tissues will be removed.

Implant surface decontamination will be performed with test (Titanium brush + 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.

Previous 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(s)**

A composite definition of successful treatment outcome defined as the absence of bleeding or suppuration on probing, absence of peri-implant probing depth  $\leq 5$  mm and mucosal recession  $\leq 1$  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

## **Key secondary outcome(s)**

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

**Completion date**

01/12/2025

## Eligibility

**Key inclusion criteria**

1. Age  $\geq$  18 years
2. Peri-implant bone defect  $\geq$ 3 mm assessed radiographically
3. Peri-implant pocket depth (PPD)  $\geq$ 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  $\geq$ 1 year in function

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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 information

## Organisation

Arrow Development S.L.

# Funder(s)

## Funder type

Industry

## Funder Name

Arrow Development S.L.

# Results and Publications

## 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?
<a href="#">Protocol file</a>			04/01/2023	No	No
<a href="#">Protocol file</a>	version 2		06/10/2025	No	No