

Non-surgical treatments for disease of the gum surrounding dental implants

Submission date 03/09/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/09/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/03/2021	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Peri-implantitis is a destructive inflammatory process affecting the soft and hard tissues surrounding dental implants. Treatment can vary significantly – from non-surgical therapy with an aim to control the infection and detoxify the implant surface, to surgical procedures to regenerate the bone that has been lost. The aim of this study is to compare the efficacy of two different non-surgical therapies (abrasive powder amino acid glycine, and a desiccant agent) and their combinations in the treatment of peri-implantitis

Who can participate?

Eligible participants are adults, aged 18 or older, suffering from initial to moderate peri-implantitis at a dental implant

What does the study involve?

The participants are randomly allocated to the glycine and desiccant agent. The two agents are combined resulting in four interventions:

1. Non-surgical debridement alone
2. Non-surgical debridement and desiccant material
3. Non-surgical debridement and glycine powder
4. Non-surgical debridement glycine powder and desiccant material

The implants are monitored for 3 years to measure the implant failure rate, implant complications, the presence of pockets between the implant and the mucosa, peri-implant bleeding, patient pain and satisfaction with the function and appearance of the implants and bone loss measured by X-ray. In addition, bacteria present near the implant are analysed.

What are the possible benefits and risks of participating?

The potential benefit is that there is no further bone loss and that the mucosa is no longer inflamed near the dental implant.

The procedure has some risks including pain and swelling around the implant site, implant failure, implant inflammation and progressive bone loss.

Where is the study run from?

Clinica Merli, Rimini (Italy)

When is the study starting and how long is it expected to run for?
May 2015 to July 2021

Who is funding the study?
This study was investigator funded

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

0.7

Study information

Scientific Title

Comparison of non-surgical treatments of peri-implant disease. Clinical and microbiological assessment in a two-factor randomised controlled trial

Acronym

FPIT

Study objectives

To compare the efficacy of two different therapies (amino acid glycine abrasive powder, and a desiccant material) and their combination in the non-surgical treatment of peri-implantitis

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/01/2016, The Ethical Committee of IRST IRCCS Area Vasta Romagna (Via Piero Maroncelli, 40, 47014 Meldola (FC), Italy; segreteriaamministrativa.ceav@irst.emr.it; +39-0543-739287), ref: 450/2016 I.5/282

Study design

Mono-centred examiner-blind randomised clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Peri-implantitis at a dental implant

Interventions

All of the patients underwent debridement with ultrasonic dedicated scalers at the dental implant. The two studied factors are:

1. Glycine powder: Abrasive powder amino acid glycine
2. Desiccant material: Application of a gel of concentrated aqueous mixture of hydroxybenzenesulfonic and hydroxymethoxybenzene acids and sulfuric acid.

This is a factorial randomised controlled trial. The two factors are combined resulting in four balanced interventions:

1. Non-surgical debridement alone (C)
2. Non-surgical debridement and desiccant material (H)
3. Non-surgical debridement and glycine powder (G)
4. Non-surgical debridement glycine powder and desiccant material (HG)

For allocation of the participants, a computer generated list of random numbers was used. A blocked randomisation was applied to include 16 patients in each of the 4 treatment groups.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

1. Abrasive powder amino acid glycine (AirFlow®, EMS, Nyon, Switzerland) 2. Desiccant material: a gel of concentrated aqueous mixture of hydroxybenzenesulfonic and hydroxymethoxybenzene acids and sulfuric acid (HybenX®, Epien Medical Inc. Saint Paul, MN, USA)

Primary outcome(s)

Measured at 6-month and 3-year follow-up:

1. Implant failure.
2. Complications (including re-treatments).
3. Change in radiographic bone level is measured using periapical intraoral radiographs taken with the parallel technique at baseline, 6 months and 3 years follow-up. Reference points for the linear measurements were the coronal margin of the implant collar and the most coronal point of bone-to-implant contact. The mesial and distal sites were averaged for each implant. The radiographic measurements were relativized considering the length of the implant. The radiographs were examined by one masked examiner.
4. Change in pocket depth is measured at 4 sites of the implant (vestibular, mesial, distal and lingual) using a PCP-15 periodontal probe (Hu-Friedy) at baseline, 6 months and 3 years follow-up.
5. Change in recession depth is measured at 4 sites of the implant (vestibular, mesial, distal and lingual) using a PCP-15 periodontal probe (Hu-Friedy) at baseline, 6 months and 3 years follow-up.
6. Bleeding on probing.

Key secondary outcome(s)

1. Pain measured using VAS will be assessed immediately after the procedure, after 1 week, after 6 months, and after 3 years.
2. Satisfaction measured using VAS after 6 months and 3 years.
3. Oral health-related quality of life measured using the Oral Health Impacts Profile (OHIP-14) after 6 months and 3 years.
4. Variation in keratinized tissue (KT) is measured at mid-buccally using a PCP-15 periodontal probe at baseline, 6 months and 3 years follow-up.
5. Variation in clinical attachment level (CAL) is registered adding the values of probing depth and recession depth at baseline, 6 months and 3 years follow-up.
6. Subgingival bacterial samples will be taken immediately before debridement and at 1 month and 6 months after debridement.

Completion date

05/07/2021

Eligibility

Key inclusion criteria

1. Aged 18 or older
2. Suffering from initial to moderate peri-implantitis at an implant site

3. Presence of at least one screw-type titanium implant exhibiting signs of moderate peri-implantitis: maximum probing depth from 5 to 8 mm bleeding on probing or suppuration in at least one site, and radiographic bone loss in at least one site
4. Radiographic infraosseous component of the defect \leq 5mm
5. Radiographic suprabony component of the defect \leq 4mm
6. Presence of at least 2 mm of keratinized mucosa
7. Implant loading of at least 6 months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

64

Key exclusion criteria

1. Patients incapable of giving informed consent
2. Mobile implant
3. Head and neck irradiated patient
4. Chemo or immunosuppressive therapy over the previous 5 years
5. Treatment with intravenous amino-bisphosphonates
6. Poor oral hygiene and motivation
7. Untreated periodontitis
8. Uncontrolled diabetes
9. Pregnancy and lactating period
10. Substance abusers
11. Allergy to chlorhexidine or phenolic or sulfur compounds
12. Smoking more than 20 cigarettes per day, or the equivalent
13. Patients unable to attend the 3-year follow-up

Date of first enrolment

09/03/2016

Date of final enrolment

05/07/2018

Locations**Countries of recruitment**

Italy

Study participating centre

Clinica Merli

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Rimini

Italy

47923

Sponsor information

Organisation

Clinica Merli

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2020	15/03/2021	Yes	No