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

Submission date
03/09/2019

Recruitment status
No longer recruiting

Registration date
18/09/2019

Overall study status
Completed

Last Edited
15/03/2021

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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; segreteriamministrativa.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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 debridment 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 measure
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.

Secondary outcome measures
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.

Overall study start date
26/05/2015

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 ≤ 5mm
5. Radiographic suprabony component of the defect ≤ 4mm
6. Presence of at least 2 mm of keratinized mucosa
7. Implant loading of at least 6 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
64

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
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Sponsor information

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Six-month follow-up results are expected to be published in a peer-reviewed journal in 2019.
Three-year follow-up results are expected to be published in a peer-reviewed journal in 2021.

Intention to publish date
14/10/2019

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