ISRCTN57998865 https://doi.org/10.1186/ISRCTN57998865

Treatment of inflamed dental implants

Submission date
31/05/2023

Recruitment status
No longer recruiting

Registration date
19/06/2023

Overall study status
Completed

Last Edited
16/06/2023

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Oral implants may develop peri-implantitis a chronic inflammation of the surrounding bone, which is caused by bacteria. If left untreated peri-implantitis leads to loss of bone and may end in the loss of the implant. Various treatment concepts have been published with limited success since it is very difficult to completely remove the bacterial biofilm from the rough endosseous surface of the device. Recently a new concept was developed, where infected implants are decontaminated by electrolytic cleaning, i.e. a weak electrical current generates hydrogen bubbles on the metallic surface, which destroys the bacterial biofilm. The aim of this study is to evaluate the clinical effect of electrolytic cleaning using the Galvosurge device on peri-implantitis lesions.

Who can participate?
Adult patients with dental implants that show signs of peri-implantitis, i.e. pus formation and peri-implant bone loss.

What does the study involve?
The study involves a comprehensive clinical and radiographic examination, microbiological sampling of the inflamed implants, conservative cleaning of all teeth and implants, surgical intervention with removal of granulation tissue and cleaning of the infected surface by electrolytic cleaning, post-operative care and follow-up controls.

What are the possible benefits and risks of participating?
The possible benefits are the healing of the lesions and the removal of local inflammation. The risks involve the recurrence of the disease as well as intra-operative and post-operative local pain.

Where is the study run from?
The Department of Periodontology at the University of Giessen as well as by the Avadent-Clinic (Germany)

When is the study starting and how long is it expected to run for?
October 2020 to March 2023

Who is funding the study?
The Department of Periodontology, Dental School, University of Giessen and Transmit GmbH (a company belonging to the university) (Germany)

Who is the main contact?
Prof. Dr. J. Meyle (Director of the Department), prof.dr.j.meyle@t-online.de

Contact information

Type(s)
Principal investigator

Contact name
Prof Joerg Meyle

ORCID ID
https://orcid.org/0000-0003-0495-6926

Contact details
Schlangenzahl 14
Giessen
Germany
35392
+49 (0)1728194362
Prof.Dr.J.Meyle@t-online.de

Additional identifiers

Protocol serial number
Galvosurge01

Study information

Scientific Title
Therapy of peri-implantitis by electrolytical decontamination

Acronym
T-PED

Study objectives
A combined surgical approach with removal of granulation tissue and electrolytical decontamination of oral implant surfaces is leading to healing of peri-implantitis lesions

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 31/03/2021, Ethical Committee of the University of Giessen (Ethik-Kommission Klinikstr. 29, Giessen, D-35385, Germany; +4964199-42470; ethik.kommission@med.uni-giessen.de), ref: AZ 24/21

Primary study design
Interventional

Study design
Bicentric prospective clinical trial

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Patients with osseointegrated oral implants with peri-implantitis lesions

Interventions
Methodology: After conservative professional cleaning and biofilm removal, a local surgical intervention with flap elevation, removal of granulation tissue and surface decontamination by electrolytical cleaning using the Galvosurge device (Nobel Biocare, Zurich, Switzerland) are performed. The defects are rinsed with hydrogen peroxide and saline. Then the flaps are closed by suturing.

Conservative professional cleaning and biofilm removal are provided face-to-face individually by a dental hygienist, who has passed professional education in this type of treatment. The intervention takes place in a dental chair in the department or in the clinic which meets all hygiene and professional standards required by the dental chamber in Germany. The participant will be asked to rinse with an antiseptic rinse (0.1% chlorhexidine solution) for 2 mins, staining will be undertaken of the biofilm deposits on the implant, and instruction will be given in performing oral hygiene measures. Removal of all deposits will occur using hand instruments, ultrasonics and air-polishing devices (EMS, Nyon, Switzerland).

Surgical intervention
The participant will be asked to rinse with an antiseptic rinse (0.1% chlorhexidine solution) for 2 mins. The surgical intervention is provided by a periodontist and oral surgeon, who has been officially acknowledged by the Dental Chamber and the National Society of Periodontology in Germany, plus a dental nurse, who is educated according to the standards for dental nurses of the Dental Chamber in Germany, assisted during surgery. The mode of intervention delivery is face-to-face individually. The intervention takes place in a dental chair with full dental equipment in the Department of the University or in the clinic which meets all hygiene and professional standards required by the dental chamber in Germany. Surgery is performed under optical magnification. Local anesthesia is provided according to the prerequisites for local surgical intervention, including the use of sterile instruments for the microsurgical approach, sterile sutures 6-0, and coverage of the patient’s face with sterile covers.

Follow-up occurs post-surgical control 2 days after surgery and 7 days after surgery for suture removal.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Galvosurge device

Primary outcome(s)
Peri-implant bleeding measured using a periodontal probe (PCPUNC 15) at baseline and at 4 weeks, and 3, 6 and 12 months after treatment

Key secondary outcome(s)
1. Peri-implant probing pocket depth measured using a periodontal probe (PCPUNC 15) at baseline and at 4 weeks, and 3, 6 and 12 months after treatment
2. Lack of peri-implant suppuration measured using visual inspection and probing the peri-implant sites at 4 weeks, and 3, 6 and 12 months after treatment
3. Reduction of the peri-implant bony defect measured using a periodontal probe by bone sounding at 6 and 12 months after treatment
4. Reduction of the red-complex bacteria in microbiological samples from the treated implants measured using 4 sterile paper points after the removal of all supra-mucosal deposits with a cotton pellet at 3, 6 and 12 months after treatment. Paper points are introduced into the peri-implant pocket until slight resistance and remain in situ for 30 secs. They are then put in sterile tubes and sent to a commercial microbiological laboratory for analysis.

Completion date
23/03/2023

Eligibility

Key inclusion criteria
1. Patients with at least one osseointegrated and functionally loaded oral implant
2. Patients with at least one implant with peri-implantitis with local signs of inflammation, i.e. bleeding upon probing w/o suppuration
2.1. Increased probing depths
2.2. Radiographically visible loss of peri-implant bone
3. Removability of the supraconstruction of the implant

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
21

Key exclusion criteria
1. Fracture of the implant
2. Malignancies
3. Mobility of the implant
4. Intake of immuno-suppressive drugs
5. Pregnancy
6. Systemic diseases with impact on treatability by local surgical interventions
7. Systemic therapy with bisphosphonates or monoclonal antibodies with impact on bone metabolism
8. Therapy with systemic antibiotics within 3 months before the study

Date of first enrolment
01/11/2020

Date of final enrolment
17/03/2022

Locations

Countries of recruitment
Germany

Study participating centre
Dental School University of Giessen
Department of Periodontology
Schlangenzahl 14
Giessen
Germany
35392

Study participating centre
Avadentklinik
Am Mühlberg 6-8
Bad Homburg
Germany
61348

Sponsor information

Organisation
University of Giessen

ROR

https://ror.org/033eqas34

Funder(s)

Funder type
University/education

Funder Name
University of Giessen

Funder Name
Transmit GmbH

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Prof. Dr. J. Meyle, Dept. Periodontology, University of Giessen, Germany, Prof.Dr.J.Meyle@t-online.de. Data will be available upon final evaluation; a set of blinded clinical data can be provided. Patient information was also submitted to the ethical committee and reviewed. Written informed consent was obtained from all patients. Each patient was assigned a number and this was used in the CRF as well as for data evaluation

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	(German)	20/07/2021	14/06/2023	No	No
Participant information sheet	PIS and consent form (German)	28/02/2021	14/06/2023	No	Yes