ISRCTN37715006 https://doi.org/10.1186/ISRCTN37715006

Comparing the effect of three different mechanical methods to clean implant surfaces to treat peri-implantitis

Submission date
15/07/2022

Recruitment status
No longer recruiting

Registration date
08/08/2022

Overall study status
Completed

Last Edited
08/08/2022

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
Peri-implantitis is an inflammation of the gums and bone around a dental implant that can lead to loss of bone. Peri-implantitis a common occurrence in clinical practice is and the frequency of this problem is increasing due to wide choices in dental implant options. Currently, there is no unified protocol that provides clear, specific steps and an effective method to treat peri-implantitis.

Who can participate?
Adult patients with peri-implantitis.

What does the study involve?
Participants will be allocated to receive one of three different mechanical methods to clean the implant surface (manual curettage, titanium brush, and diode laser) during the procedure, with an equal chance of receiving each. At 6 months after surgery, the participants will undergo clinical and radiological assessments to evaluate the effectiveness of each method.

What are the possible benefits and risks of participating?
The main benefit of this study is the possibility to receive a recommendation for, and treatment with, the most effective method to use in treating peri-implantitis. There is a risk of not achieving good results in some cases, however, due to the follow-up period of 6 months post-operation, the study team can manage these cases.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
From May 2022 to April 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Kenan Saoud, kenan.saoud@outlook.com

Contact information

Type(s)
Scientific

Contact name
Dr Kenan Saoud

ORCID ID
http://orcid.org/0000-0002-6146-9756

Contact details
Damascus University
Al-Mazzeh Highway
Damascus
Syria
-
+963 966600565
kenan.saoud@outlook.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A comparative study to evaluate the efficacy of three different methods of peri-implantitis surgical regenerative interventions

Study objectives
Do the three methods used in this research to treat implant surfaces have clinical and radiographical differences?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2022, Scientific Research Committee Faculty of Dentistry at Damascus University (Mazzeh Highway, Damascus, Syria; +963113341864; manager@hcsr.gov.sy)

Study design
A comparative interventional randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional file

Health condition(s) or problem(s) studied
Peri-implantitis

Interventions
First, cases will be diagnosed clinically and radiographically to ensure the matching of inclusion criteria.
After local anesthesia, a full thickness flap will be made in the implant site, and the affected areas around the implant will be determined. Participants will be randomised to receive one of the three selected mechanical methods (manual curettage, titanium brush, and diode laser). For all participants, this will then be followed by chemical agents EDTA 19% and local antibiotic, and covering implants surface with the bone graft then confirm a very tight closure.
The randomization of the sample will be done by giving a number for each acceptable case within the research and placing a letter numbering for the three research groups, a case number will be drawn with a corresponding of letters to determine the method of work for each case.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Microscopic topography of the implant surface formed after applying each method of mechanical treatments measured using scanning electronic microscope SEM at baseline and 6 months after the grafting process
2. Dimensions of the grafted alveolar ridge in the area of the implant at the transverse plane measured (clinically) using cone-beam computed tomography systems (CBCT) the day following the surgery and 6 months after the grafting process
3. Dimensions of the grafted alveolar ridge in the implantation area at the transverse and vertical levels measured using cone-beam computed tomography systems (CBCT) at baseline

and 6 months after the grafting process
4. Gingival health measured using assessment of gingival indices, bleeding on probing (BOP), and peri-implant pocket depth (PPD) at baseline and 6 months after the grafting process

Secondary outcome measures
1. Effect on the keratinized gingiva measured using keratinized gingival width will be measured by a periodontal probe from a reference point at the buccal side of the implant (mid buccal surface of the gingival former) to the MGJ (muco-gingival junction) before the surgery and 6 months after the grafting process
2. Pain after surgery measured using a visual analogue score (VAS) at baseline, 24 h, 48 h, and one week after surgery at baseline and 6 months after the grafting process
3. Patient satisfaction with the surgical procedure measured using patient satisfaction questionnaire (PSQ-18) at 6 months after the grafting process

Overall study start date
15/05/2022

Completion date
15/04/2024

Eligibility

Key inclusion criteria
1. ≥1 implant with peri-implantitis with a peri-implant pocket depth ≥6 mm, bleeding on probing, and bone loss of <50% of the implant's surface area
2. The surface of the affected dental implant is treated with acid etching and sandblasting (SLA) technique
3. The bone defect surrounding the implant is ≥2 walls and is estimated to be ≥3 mm of the implant length
4. Good oral health
5. No periodontitis on remaining teeth and no history of periodontitis leading to the loss of teeth
6. Presence of a gum strip adhered to the implant area of ≥2 mm

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Between 30 and 36 patients

Key exclusion criteria
1. Implant movement
2. An excessive occlusal load on the implant
3. Being treated with drugs that cause bone metabolism disorder such as corticosteroids, oral contraceptives, hormonal and chemical treatments, or have undergone radiotherapy in the face

area
4. Pregnancy or breastfeeding
5. Smoking (>10 units per day)
6. General systemic diseases (such as diabetes, cardiovascular disorders, leukemia, high arterial tension, coagulation disorders, and metabolic diseases)

Date of first enrolment
01/08/2022

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
Syria

Study participating centre
Faculty of Dentistry of Damascus University
Al-Mazzeh highway
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

Sponsor details
Al-Mazzeh Highway
Damascus
Syria
-
+963113341864
manager@hcsr.gov.sy

Sponsor type
University/education

Website
http://damasuniv.edu.sy/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Publication and dissemination plan
Planning publication of the research results.

Intention to publish date
01/09/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available on request from Dr Kenan Saoud, kenan.saoud@outlook.com and in the publication related to it after the end of the research.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	In Arabic language		08/08/2022	No	Yes