Calcium phosphate granules in treatment of peri-implantitis

Submission date	Recruitment status No longer recruiting	Prospectively registered		
05/10/2018		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
24/10/2018	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
26/11/2019	Oral Health			

Plain English summary of protocol

Background and study aims

Implant based treatment is an important part of modern dentistry. Loss of bone around dental implants can happen in 5–10% of patients. Peri-implantitis is an infection that causes bone loss around a dental implant. The optimal result of peri-implantitis treatment is regeneration of hard and soft tissues supporting the dental implant. The aim of study is to analyse the results of peri-implantitis treatment, where in addition to the classical surgical treatment, the bone defect around the dental implant was filled with bioceramic granules developed and produced by Riga Technical University (RTU), Rudolfs Cimdins Riga Biomaterials Innovation and Development Centre.

Who can participate?
Adults with peri-implantitis

What does the study involve?

All participants receive the same treatment - mechanical cleaning of the implant surface and filling of bone defect with bioceramic granules. All patients will have a radiological investigation before the treatment and at least five years after the treatment.

What are the possible benefits and risks of taking part in this study? From enrolling in this study, the participants get complex treatment with the use of new biomaterials, which may better treat their peri-implantitis. There are no known risks to participants taking party in this study.

Where is the study run from? Riga Stradiņš University Institute of Stomatology (Latvia)

When is the study starting and how long is it expected to run for? September 2012 to May 2018

Who is funding the study?

- 1. Riga Stradiņš University (Latvia)
- 2. National Research Programme No 2014.10-4/VPP-3/21 'Multifunctional Materials and

Composites, Photonics and Nanotechnology (IMIS2)' Project No 4 "Nanomaterials and Nanotechnologies for Medical Applications" (Latvia)

Who is the main contact? Vadims Klimecs vadims.klimecs@gmail.com

Contact information

Type(s)

Scientific

Contact name

Mr Vadims Klimecs

Contact details

Dzirciema street 20 Riga Latvia LV 1007

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 2013/02

Study information

Scientific Title

Radiological evaluation with 3D cone-beam computed tomography of bone loss around dental implants in 18 patients 5 years after implantation of biphasic calcium phosphate (HAP/ β TCP) granules

Study objectives

Implantation of biphasic calcium phosphate (HAP/ β TCP) granules around dental implants in patients with peri-implantitis will stimulate regeneration of hard tissue.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Riga Stradiņš University Commission of Ethics, 04/09/2014, Nr. E-9(2)/24.07.2014

Study design

Interventional single-centre non-randomised study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Bone loss around dental implants - peri-implantitis

Interventions

Patients underwent treatment by the following surgical protocol:

- 1. Systemic antibiotics 3 times per day for 2 days before surgery
- 2. Preoperative rinse for 1 minute with a 0.2% chlorhexidine solution
- 3. Local anaesthesia with Articaine solution
- 4. Designing of mucoperiostal flap
- 5. Determining the size of the infected area
- 6. Mechanical cleaning and curettage of the implant surface
- 7. Application of a gauze pad moistened with a 2% chlorhexidine solution in the area of bone defect for 5 minutes
- 8. After removing the gauze swab, the defect is washed by 1 g of tetracycline dissolved in 20 ml of sterile physiological solution
- 9. Filling of bone defect with bioactive material HAp/ β -TCP
- 10. Wound closure with a surgical suture
- 11. Systemic antibiotics 3 times per day for 3 days after surgery

The treatment will last for one operation and there will be a 5 year follow-up period.

Intervention Type

Procedure/Surgery

Primary outcome measure

Alveolar bone density, assessed using 3D CT scans before the operation and 5 years after the operation

Secondary outcome measures

Percentage of bone tissue loss, assessed using 3D CT scans before the operation and 5 years after the operation

Overall study start date

01/09/2012

Completion date

30/05/2018

Eligibility

Key inclusion criteria

- 1. Peri-implantitis at any stage
- 2. Use of biphasic calcium phosphate (HAP/βTCP) granules produced in Riga Technical University Rudolfs Cimdins Riga Biomaterials Innovation and Development Centre
- 3. Presence of a 3D CT before the treatment
- 4. Aged 40-71 years

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

20 patients

Key exclusion criteria

N/A

Date of first enrolment

01/02/2013

Date of final enrolment

01/05/2013

Locations

Countries of recruitment

Latvia

Study participating centre

Riga Stradins University Institute of Stomatology

Dzirciema Street 20

Riga

Latvia

LV 1007

Sponsor information

Organisation

Riga Stradinš University

Sponsor details

Dzirciema Street 16 Riga Latvia LV 1007 +37167409258 zd@rsu.lv

Sponsor type

University/education

Website

www.rsu.lv

ROR

https://ror.org/03nadks56

Funder(s)

Funder type

University/education

Funder Name

Riga Stradiņš University

Funder Name

National Research Programme No 2014.10-4/VPP-3/21 'Multifunctional Materials and Composites, Photonics and Nanotechnology (IMIS2)' Project No 4 'Nanomaterials and Nanotechnologies for Medical Applications'.

Results and Publications

Publication and dissemination plan

We intend to publish the main results of the radiological investigation Journal of Healthcare Engineering in 2018

Intention to publish date

20/12/2018

Individual participant data (IPD) sharing plan

Participant data will be available upon request from Vadims Klimecs (vadims.klimecs@gmail. com) in accordance with General Data Protection Regulation (GDPR).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/12/2018	06/11/2019	Yes	No