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Calcium phosphate granules in treatment of peri-implantitis

Submission date	Recruitment status	[_] Prospectively registered
05/10/2018	No longer recruiting	[_] 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?
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Contact information

Type(s)
Scientific

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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/βTCP) granules

Study objectives
Implantation of biphasic calcium phosphate (HAP/βTCP) 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
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Sponsor information

Organisation
Riga Stradiņš University

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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