

# Calcium phosphate granules in treatment of peri-implantitis

<b>Submission date</b> 05/10/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/10/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/11/2019	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## 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 Cimdinis 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 part 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

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LV 1007

## Additional identifiers

### Protocol serial number

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/ $\beta$ TCP) granules

### Study objectives

Implantation of biphasic calcium phosphate (HAP/ $\beta$ 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

**Study type(s)**

Treatment

**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 mucoperiosteal 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/ $\beta$ -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(s)**

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

**Key secondary outcome(s)**

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

**Completion date**

30/05/2018

**Eligibility****Key inclusion criteria**

1. Peri-implantitis at any stage
2. Use of biphasic calcium phosphate (HAP/ $\beta$ TCP) 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

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LV 1007

## Sponsor information

**Organisation**

Riga Stradiņš University

**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

## 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?
<a href="#">Results article</a>	results	05/12/2018	06/11/2019	Yes	No