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Surgery of failing dental implants using two different brands of bovine bone chips

Submission date	Recruitment status	[_] Prospectively registered
17/02/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/02/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/09/2020	Oral Health	

Plain English summary of protocol

Background and study aims
Peri-implantitis is an inflammatory and infectious disease of the supporting soft and hard tissues around a dental implant, characterized by bleeding and/or suppuration on probing and crestal bone loss. Due to the progressive nature of the inflammatory process rapid loss of supporting bone, impaired oral function and even implant loss can occur. Prevalence of peri-implantitis on patient level is high, varying from 16% up to 56% depending on the threshold set for disease definition.

Who can participate?
Adults with peri-implantitis.

What does the study involve?
Participants will be randomly allocated to receive treatment with Endobon® Xenograft Granules using a "non-submerged" regenerative surgical approach according to the specified procedure, or similar treatment with an established bovine derived bone mineral.

What are the possible benefits and risks of participating?
If the treatment is successful, the implant can be saved; new bone will be regenerated and the implant will have enhanced bone support. The bone substitutes are free of cost for the patient. The risks associated with taking part in this clinical study are no greater than with ordinary gum surgery (flap operation). There may be some bleeding, pain and swelling for the first few days after the procedure. There is also a risk that the bone substitutes will not anchor sufficiently. If this happens the material will be removed and ordinary flap operation will take place without any extra costs for the patient.

Where is the study run from?
Department of Periodontology, Academic Centre for Dentistry Amsterdam (ACTA) (Netherlands)

When is the study starting and how long is it expected to run for?
July 2015 to May 2019

Who is funding the study?
1. Department of Periodontology ACTA (Netherlands)
2. ZimmerBioMet (USA)

Who is the main contact?
Dr Angeliki Polymeri
a.polymeri@acta.nl

Contact information

Type(s)
Scientific

Contact name
Dr Angeliki Polymeri

ORCID ID
https://orcid.org/0000-0002-5583-0365

Contact details
Department of Periodontology, ACTA,
Gustav Mahlerlaan 3004
Amsterdam
Netherlands
1081 LA
+31205980322
a.polymeri@acta.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NL51525.029.15

Study information

Scientific Title
The regenerative surgical treatment of intra-bony peri-implantitis defects with Endobon® (test) versus an established bovine derived bone mineral (control) – a pilot study

Study objectives

The peri-implantitis patients treated with Endobon® Xenograft Granules (Biomet 3i) will perform non-inferior in new bone formation around dental implants than the established bovine-derived bone mineral (Bio-Oss®)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/07/2015, Ethical committee of the VU Medical Centre, Amsterdam (Medisch Ethische Toetsingscommissie, VU Medisch Centrum, Postal address: Postbus 7057, 1007 MB Amsterdam
the Netherlands; +31204445585; e-mail: metc@vumc.nl), ref: NL51525.029.15

Study design
Randomized controlled single-blinded prospective clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files (in Dutch)

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

Interventions
Test patients are treated with Endobon® Xenograft Granules using a "non-submerged" regenerative surgical approach according to the specified procedure, and control patients treated similarly with an established bovine derived bone mineral. The study will be randomized using block design which will insure that the number of subjects receiving the different treatments is randomly and evenly allocated.

Intervention Type
Procedure/Surgery

Primary outcome measure
Vertical radiographic bone fill of peri-implant intra-bony defects measured on the basis of standardized intraoral periapical radiographs at at baseline, 6 months and 12 months

Secondary outcome measures

All measured at 6 sites/implant at baseline, 6 months and 12 months:
1. Pocket probing depth
2. Bleeding on probing
3. Dichotomous scoring of suppuration (pus)
4. Dichotomous scoring of plaque

Overall study start date
01/04/2013

Completion date
16/05/2019

Eligibility

Key inclusion criteria
1. During surgical exploration an intra-bony component of at least 3 mm at the deepest point must be present.
2. The defect should have a minimum of 3 osseous walls (a circumference of the osseous defect of at least 270 degrees). Only 3 and 4 wall intraosseous defects will be included
3. The defect must not be wider than 4 mm and the defect angle must be less than 35 degrees from axis of implant
Note: If the same patient has more than one defect meeting the inclusion criteria only one such defect will be included in the study and the other defects will be treated with standard open flap debridement

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Total final enrolment
25

Key exclusion criteria
1. Diabetes mellitus (HbAlc ≥ 6.5%)
2. Taking corticosteroids or other anti-inflammatory prescription drug
3. Taking medications known to induce gingival hyperplasia
4. Allergic to penicillin or metronidazole
5. History of taking systemic antibiotics in the preceding month
6. Pregnant or lactating

7. Stability of the Endobon® granules or control granules cannot be accomplished in the defect
8. Failure of obtaining soft tissue closure
9. Mobile implants

Date of first enrolment
29/07/2015

Date of final enrolment
07/06/2018

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Centre for Dentistry Amsterdam (ACTA),
Department of Periodontology
University of Amsterdam and Vrije Universiteit
Gustav Mahlerlaan 3004
Amsterdam
Netherlands
1081LA

Sponsor information

Organisation
Academic Center for Dentistry Amsterdam

Sponsor details
University of Amsterdam and Vrije Universiteit Amsterdam
Gustav Mahlerlaan 3004
Amsterdam
Netherlands
1081 LA
+31 205980322
paro@acta.nl

Sponsor type
University/education

Website
https://www.acta.nl

ROR

https://ror.org/04x5wnb75

Funder(s)

Funder type
University/education

Funder Name
Academic Centre for Dentistry Amsterdam (ACTA)

Funder Name
ZimmerBioMet

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/05/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		10/02/2015	06/03/2020	No	Yes
Results article	results	01/11/2020	11/09/2020	Yes	No