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

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Our main objective is to evaluate and compare appliance of Endobon® Xenograft Granules (Biomet 3i) with an established bovine derived bone mineral for regeneration of intra-bony peri-implantitis defects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42142

Source
ToetsingOnline

Brief title
Endobon versus BioOss

Condition

- Other condition

Synonym
peri-implant bony defects, peri-implant infection

Health condition

infecties rondom tand implantaten

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Biomet 3i

Intervention

Keyword: bone defects, peri-implantitis, regeneration, treatment

Outcome measures

Primary outcome

The main study parameter is radiographic vertical reduction of the intra-bony peri-implantitis defects for test and control groups at 6 and 12 months after surgery. The difference in defect fill will be measured on the basis of standardized intra-oral periapical radiographs taken with individualized holders at baseline, and 6 and 12 months after surgery.

Secondary outcome

The secondary objectives to evaluate are:

1) clinical parameters (pocket probing depth [PPD], clinical attachment level [CAL] from stent margin, bleeding on probing, presence /absence pus)

2) patient centered outcomes (subjective satisfaction)

3) graft morbidity

4) esthetics

Study description

Background summary

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.
For peri-implantitis intra-bony defects, bone substitutes may give additional implant support and stability. We hypothesize that the peri-implantitis patients treated with Endobon® Xenograft Granules (Biomet 3i) will regenerate more new bone around dental implants than the established bovine derived bone mineral.

Study objective

Our main objective is to evaluate and compare appliance of Endobon® Xenograft Granules (Biomet 3i) with an established bovine derived bone mineral for regeneration of intra-bony peri-implantitis defects.

Study design

This is a randomized controlled prospective, clinical trial of 12 months follow-up at the Sections of Periodontology and Oral Implantology of the Academic Center for Dentistry Amsterdam (ACTA).

Intervention

We will treat 20 test patients with Endobon® Xenograft Granules using a "non-submerged" regenerative surgical approach according to the specified procedure, and 20 control patients treated similarly with an established bovine derived bone mineral.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• During surgical exploration an intra-bony component of at least 3 mm at the deepest point must be present.
• 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.
• The defect must not be wider than 4 mm and the defect angle must be less than 35 degrees from axis of implant.

Exclusion criteria

• Subjects with diabetes mellitus (HbAlc >= 6.5%)
• Subjects taking corticosteroids or other anti-inflammatory prescription drug
• Subjects taking medications known to induce gingival hyperplasia
• Subjects must not be allergic to penicillin or metronidazole
• Subjects with a history of taking systemic antibiotics in the preceding month
• Subjects must not be pregnant or lactating
• Implants placed in grafted bone or previously augmented with bone substitute or other type of regenerative material

• If stability of the Endobon® granules or control granules cannot be accomplished in the defect
• Failure of obtaining soft tissue closure
• Mobile implants

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	mineral granules/bone substitute
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-07-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-12-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL51525.029.15