OsteoActivator-P for accelerated localized alveolar ridge preservation

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29312

Source
NTR

Brief title
OsteoActivator-P for accelerated localized alveolar ridge preservation

Health condition

Healthy patients with a ruinous dentition (including the canines) in the lower jaw in need of extractions of all teeth of the mandible.

Sponsors and support

Primary sponsor: Osteo Pharma
Source(s) of monetary or material Support: Osteo Pharma

Intervention

Outcome measures

Primary outcome

• To histologically assess and compare new bone formation and bone quality 8 weeks after socket preservation with OsteoActivator-P porcine pericard membranes containing alendronate and testosterone to Collagen Membrane-P uncoated.
• To assess the safety of the use of OsteoActivator-P porcine pericard membranes in the

treatment of alveolar ridge preservation.

Secondary outcome

• To assess and compare new bone formation and bone quality by computed tomography 8 weeks after socket preservation with OsteoActivator-P porcine pericard membranes containing alendronate and testosterone to Collagen Membrane-P uncoated.
• To determine the ease of use of OsteoActivator-P porcine pericard membranes for alveolar ridge preservation.
• Implant site inspection
• To assess reliable implant placement at 8 weeks with application of OsteoActivator-P porcine pericard membranes containing alendronate and testosterone as compared to standard of care (Collagen Membrane-P uncoated).
• Implant Stability Quotient (ISQ) at implantation and after 12 weeks.
• Patient satisfaction

Study description

Background summary

Rationale
Collagen barrier membranes are widely used for ridge preservation applications. Once an extraction socket is filled with a bone filler and covered by a collagen membrane, guided bone regeneration (GBR) is observed due to the barrier function of the membrane, allowing implant placement after a certain time period. Due to the addition of a PLGA coating containing ancillary amounts of alendronate and testosterone to a collagen membrane, bone formation is stimulated, which is expected to further accelerate GBR allowing implants to be placed at an earlier timepoint.

Overall hypothesis
The use of OsteoActivator-P porcine pericard collagen membranes compared to Collagen Membrane-P uncoated will result in accelerated bone formation as shown by histologic analysis at 8 weeks after socket preservation. This will enable reliable and safe implant placement at an earlier timepoint after socket preservation.

Objectives
• To histologically assess and compare new bone formation and bone quality 8 weeks after socket preservation with OsteoActivator-P porcine pericard membranes containing alendronate and testosterone to Collagen Membrane-P uncoated.
• To assess the safety of the use of OsteoActivator-P porcine pericard membranes in the treatment of alveolar ridge preservation.
• To assess and compare new bone formation and bone quality by computed tomography 8 weeks after socket preservation with OsteoActivator-P porcine pericard membranes containing alendronate and testosterone to Collagen Membrane-P uncoated.

• To determine the ease of use of OsteoActivator-P porcine pericard membranes for alveolar ridge preservation.
• Implant site inspection
• To assess reliable implant placement at 8 weeks with application of OsteoActivator-P porcine pericard membranes containing alendronate and testosterone as compared to standard of care (Collagen Membrane-P uncoated).
• Implant Stability Quotient (ISQ) at implantation and after 12 weeks.
• Patient satisfaction

Trial Design
This is a prospective, randomized, standard of care controlled clinical trial.

Intervention groups
This will be a split mouth study design. The alveolar ridge preservation will be applied on the two canine regions of the mandible. The alveolar extraction sockets of the canines will be filled with a xenogenic bone substitute. Upon randomization the experimental side will be covered with OsteoActivator-P, the extraction socket filled with xenogenic bone on the control side will be covered with Collagen Membrane-P uncoated.
Implant placement in the mandibular canine regions will take place 8 weeks after extraction and socket preservation.

Experimental:
OsteoActivator-P: PLGA-coated collagen membrane containing alendronate (Aln) 20 µg/cm2 and testosterone (T) 125 µg/cm2.
Control:
Standard of Care (SoC): Uncoated collagen membrane (Collagen Membrane-P uncoated)

Study objective

The use of OsteoActivator-P porcine pericard collagen membranes compared to Collagen Membrane-P uncoated will result in accelerated bone formation as shown by histologic analysis at 8 weeks after socket preservation. This will enable reliable and safe implant placement at an earlier timepoint after socket preservation.

Study design

Visit 0: Screening visit
• The screening visit will be performed at least 1 day before the operation. The following procedures will be performed:
• Informed consent
• Medical history
• Orthopanthomogram
• Medication review
• Verification of inclusion/exclusion criteria

Visit 1: Operation day (Day 1)
Pre-operatively:

• Medical history
• Medication review
• Verification of inclusion and exclusion criteria
Post operation
• Cone Beam CT
• Extraction of all teeth in the mandible, alveolotomy and ridge preservation of the canine sites
• Ease of use questionnaire
• AEs / device deficiencies

Visit 2: at 2 (±1) weeks
• AEs / device deficiencies
• Wound inspection

Visit 3: at 8 (±1) weeks
• Cone beam CT
• Placement dental implants at canine regions
• Biopsy
• ISQ measurement
• Implant site inspection
• Wound inspection
• AEs / device deficiencies

Visit 4: at 10 (±1) weeks
• Implant site inspection
• AEs / device deficiencies
• Wound inspection

Visit 5: at 20 (±1) weeks
• Cone Beam CT
• Implant site inspection
• ISQ measurement
• Start manufacturing prosthesis.
• Exposure of the implants and placement abutment

Visit 6 and 7: 34 and 60(±1) weeks
• Patient satisfaction
• Implant site inspection

Intervention

This will be a split mouth study design. The alveolar ridge preservation will be applied on the two canine regions of the mandible. The alveolar extraction sockets of the canines will be filled with a xenogenic bone substitute. Upon randomization the experimental side will be covered with OsteoActivator-P, the extraction socket filled with xenogenic bone on the control side will be covered with Collagen Membrane-P uncoated.
Implant placement in the mandibular canine regions will take place 8 weeks after extraction

and socket preservation.

After obtaining informed consent, patients with a ruinous dentition in the lower jaw and in need of an implant based lower prosthesis and meeting all inclusion criteria and none of the exclusion criteria, will be enrolled in the study. The estimated duration of this study from first intake till last follow-up is about 60 weeks. The extraction procedure will take place using local anaesthesia (ultracain D-S Forte). The teeth in the mandible will be removed and a alveolotomy is achieved for preprosthetic preparation. At least 7mm of the alveolar extraction socket in the region of the canines will be left after the alveolotomy.
These extraction sockets at the canine regions will be filled with xenogenic bone substitute material (Bio-Oss®) and be covered upon randomization with the standard Collagen Membrane-P uncoated while the contralateral side is covered with OsteoActivator-P. Subsequently, all wounds will be closed with Vicryl® 3-0. After treatment, a Cone Beam Computed Tomography (CBCT) is performed. All patients receive antibiotic treatment for one week (Amoxicillin and Clavulanic Acid 3 times a day 500/125 mg. In case of allergies Clindamycin 4 times a day 300 mg). Ease of use questionnaire will be filled in by the surgeon. Eight weeks after alveolar ridge preservation a CBCT is performed. Bone biopsies are taken with a trephine drill right before placing the implants. Straumann Bone Level® implants are placed. ISQ will be measured when the implants are placed. Finally, the wounds will be closed with Vicryl® 5-0. Two weeks after implant placement the wounds are inspected, and sutures are removed.
We chose for a two-staged procedure concerning implant placement. A two-stage procedure is used when more of a margin of safety is required. With this approach, the implants are placed in the bone and afterwards covered with the mucosal tissue. They are not exposed to the mouth but stay buried for and left to heal. This approach is used when poorer bone quality or quantity is expected. During the healing time regeneration of bone around the implant will take place, resulting in a good implant osseointegration. This procedure will provide a safe healing time for both implants in this study.
Twelve weeks after implant placement a CBCT is made again and the implants are exposed in a second look operation. The ISQ will be measured before the implants are provided with abutments. In this stadium the dental lower prosthesis can be manufactured by the dentist. The patient will return for a regular check-up visit at 26 and 52 weeks after implantation.

Contacts

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Eligibility criteria

Inclusion criteria

• Males and females, aged ≥18 years.
• Patient has signed informed consent.
• Patients with a ruinous dentition (including the canines) in the lower jaw in need of extractions of all teeth of the mandible.
• Patients in need of a total dental prosthesis in the lower jaw.
• Patients that want an implant-based denture in the lower jaw.
• Bone width of at least 7mm
• Bone height beneath the root-point of the canines at least 10mm

Exclusion criteria

• Absence of the lower canines
• History of treatment with bisphosphonates or denosumab
• History of radiotherapy in the head/neck region
• Poor oral hygiene
• Women who are pregnant or breastfeeding
• Compromised immune system (e.g. uncontrolled diabetis) or unstable bleeding disorder.
• Patients with ASA classification of III or worse
• Local infection at the site of implantation
• History of previous ridge augmentation/preservation at the site of interest
• History of oral cancer or radiation of the oral cavity.
• Current malignancy
• Unresolved oral pathologies
• Refusing the implantation of porcine material
• Highly atrophic mandible (Cawood classification V or higher)
• Known allergy to collagen.
• Heavy smoking (> 20 cigarettes/day).

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2021
Enrollment:	16
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 51997
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9346
CCMO	NL76937.068.21

Register	ID
OMON	NL-OMON51997

Study results