Periosteal elevation in maxilla augmentation.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21889

Source
Nationaal Trial Register

Health condition

At the department Cranio-Maxillofacial Surgery of Maastricht University Medical Center (MUMC) the routine procedure for sinus floor elevation prior to dental implant insertion is augmentation with a mixture of autogenous bone and xenogenous bone, which adds morbidity due to the donorsite.
We want to augment the maxillary sinuses without using any substitutes by placing only a resorbable barrier to elevate the Schneiderian membrane of the floor of the sinus. Bone will be regenerated using the periosteal capacity of osteoinduction.

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Maastricht University Medical Center

Intervention

Outcome measures

Primary outcome

CBCT:

Computed tomographic follow-up is used for the evaluation of the bone amount and quality (28). A cone beam computed tomography (CBCT) will be made pre-operatively.

Four months postoperative a CBCT will be made. This will be necessary prior to implant insertion regardless to the chosen technique of augmentation. On this scan a direct comparison of bone height and volume can be made between the two augmented sinuses. Inserting implants in the maxilla follows this procedure.

Four months after placing the implants a CBCT will be made to evaluate the bone quality surrounding the implants.

Histology:

During the regular procedure of implant insertion a canal must be drilled. During this study we will use the bone that is removed before insertion for histological research. Instead of using a solid burr for the preparation of the implant beds, we will use a trephine burr (diameter 3.5mm). This is a hollow shaped burr that allows us to take a bone core for histological evaluation before implant placement. No bone loss or extra defects are created.

Secondary outcome

Secondary endpoints are implant survival, prosthetic rehabilitation and patient's satisfaction.

We will also observe the appearance of complications like infection, bleeding and pain.

Study description

Background summary

Rationale:

At the department Cranio-Maxillofacial Surgery of Maastricht University Medical Center (MUMC) the routine procedure for sinus floor elevation prior to dental implant insertion is augmentation with a mixture of autogenous bone and xenogenous bone, which adds morbidity due to the donorsite.
We want to augment the maxillary sinuses without using any substitutes by placing only a resorbable barrier to elevate the Schneiderian membrane of the floor of the sinus. Bone will be regenerated using the periosteal capacity of osteoinduction.

Hypothesis:

In the atrophic maxilla periosteal elevation with a resorbable membrane in the sinuses creates sufficient and reliable bone for later dental implant insertion.

Objective:

To compare the efficacy of two different techniques for the augmentation of the atrophic maxilla.

Study design:

This is a pilot randomized controlled clinical trial.

Study population:

Healthy human edentulous volunteers (18 -75yr old) with bilateral atrophy of the maxilla and insufficiency of the upper dental prosthesis will be included in this study.

Intervention:

This will be a split mouth study design. The sinus will be approached by the lateral window technique. On one side a resorbable barrier will be placed to create a space which will be replaced through newly formed bone. On the contralateral side a mixture of autogenous bone from the anterior iliac crest and xenogenic bone is used to augment the sinus.

Main study parameters/endpoints:

The main study parameter is the difference of the amount of bone formation, measured with a cone beam CT, between the two sides of the maxillary sinuses.

A cone beam CT will be made pre-operative and 4 months post-operative. One last cone beam CT will be produced 4 months after implant insertion.
The bone quality will be evaluated by bone histology, taken at the moment of implant placement.

Other endpoints will be implant survival, prosthetic survival and patient’s satisfaction.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The patient must visit the clinic as often as in a standard treatment. No extra visits are needed.
The benefit of participating in this study is less donor site morbidity, because only half of the amount of autogenous bone is grafted. Second benefit is that the risk related to the use of xenogenous bone substitutes is reduced (slow sinus infections, Creutzfeldt-Jakob disease, etc.).
The risk associated with participation is the presence of insufficient bone in the sinus site with periosteal elevation. In this scenario a second surgery may be needed.

Study objective

In the atrophic maxilla periosteal elevation with a resorbable membrane in the sinuses creates sufficient and reliable bone for later dental implant insertion.

Study design

1. Intake patient; informed consent; permission; CBCT;

2. Sinus floor augmentation in general anaesthesia → split mouth design;

3. 4 months post-op: CBCT;

4. 4-6 months post-op: Bone for histological research; implant insertion;

5. 4 months post-insertion: CBCT;

6. 4-6 months post-insertion: Loading implants
6 months post-loading, Implant stability; prosthetic survival; patient’s satisfaction;

7. 1 year post-loading : Implant stability; prosthetic survival; patient’s satisfaction.

Intervention

With this study we want to evaluate the bone quantity and quality after periosteal elevation of the Schneiderian membrane. We want to compare these results with sinus augmentation with a mixture of autogenous bone and xenogenous bone. This will be a split mouth design for direct comparison of bone quality and implant survival.

The resorbable membrane that we want to use for the stabilization of the elevated sinus is made of poly(D,L) lactide (PDLLA). This material is common used in the fixation of fractures during trauma surgery. It is a material of great interest because of its proven biocompatibility

and high initial mechanical strength and was tested in different clinical studies. PDLLA has the advantage of degradation without generation of any crystalline remnants.

The membrane is 40 x 40 x 0,2 mm and is perforated. When the membrane is heated, it can be formed in the right shape that is suitable to create a stable periosteal elevation in de sinus.

Contacts

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Eligibility criteria

Inclusion criteria

1. 18-75 years old;

2. Edentulous;

3. Residual bone heights of 1-8 mm;

4. Bone width of at least 5 mm.

Exclusion criteria

1. Contraindications for general anaesthesia;

2. History of radiotherapy in the head/neck region;

3. Treated with bisphosphonates;

4. Poor oral hygiene;

5. Uncontrolled diabetes;

6. Pregnancy;

7. Infection;

8. Increased tendency to hemorrhages.

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):	20-01-2013
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-11-2012

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36997
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3541
NTR-old	NTR3696
CCMO	NL41286.068.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36997

Study results

Summary results
N/A