Augmentation of the maxillary sinus floor: periosteal elevation versus autogenous bone and xenogenic material

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

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

Summary

ID

NL-OMON36997

Source
ToetsingOnline

Brief title
Periosteal elevation

Condition

- Other condition

Synonym
Maxillary atrophy

Health condition

Protheseinsufficiëntie ivm atrofie van de maxilla

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Maxilla atrophy, Sinus floor augmentation

Outcome measures

Primary outcome

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.

Secondary outcome

Other endpoints will be implant survival, prosthetic survival and patient*s

satisfaction.

Study description

Background summary

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.

Study objective

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

Study design

This is a pilot randomised controlled clinical trial

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 other side a mixture of autogenous bone from the crista iliaca anterior and xenogenic bone is used to augment the sinus.

Study burden and risks

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.

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

18-75 years old
Edentulous
Residual bone heights of 1-8 mm
Bone width of at least 5 mm

Exclusion criteria

Contraindications for general anaesthesia
History of radiotherapy in the head/neck region
Treated with bisphosphonates
Poor oral hygiene
Uncontrolled diabetes
Pregnancy
Infection

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-12-2012
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	resorbable membrane;poly(D;L) lactide (PDLLA)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-12-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21889
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL41286.068.12
OMON	NL-OMON21889