The use of β-TCP (bèta-tricalcium phosphate) as a filler of the autologous symphyseal bone graft harvest site in patients undergoing grafting of alveolar clefts in CLAP(Cleft Lip Alveolus Palate) patients

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

Summary

ID

NL-OMON30182

Source
ToetsingOnline

Brief title
Grafting CLAP patients with bèta-TCP (bèta-tricalcium phosphate)

Condition

- Other condition
- Congenital and hereditary disorders NEC
- Head and neck therapeutic procedures

Synonym
alveolus and palate/Harelip, Cleft of lip

Health condition

cheilognathopalatoschisis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Progentix

Intervention

Keyword: alveolus and palate, autologous graft, bèta-TCP(bèta-tricalcium phosphate), cleft of lip, substitute bone

Outcome measures

Primary outcome

The outcome of the study will be the difference(%) in volumetrically(sq mm)

assessed bone volume compared to the original bone volume.

Secondary outcome

not applicable

Study description

Background summary

At approximately 11 years of age patients with cleft of lip, alveolus and palate will undergo bonegrafting surgery in order to close the alveolar cleft with autologous chin bone or with iliac crest bone before orthodontic interference takes place. These harvest sites require a second additional surgical procedure with risk of primary and secondary complications. Therefore the use of a synthetic, osteoinductive material seems a logical step forward.

Study objective

This current study aims to investigate the use of bèta-TCP, a synthetic tricalcium phosphate, as a filler of the autologous symphyseal bone graft harvest site in patients undergoing grafting of clefts of lip, alveolus and palate.
The specific properties of Progentix TCP result in optimal and predictable bone regeneration as also proven in the human situation.
It seems meaningful to introduce the bèta-TCP first of all in the harvest site in which bone has to be regenerated and no orthodontic interference will be performed.

Study design

-indication for grafting the alveolar cleft in the patient with cleft of lip, alveolus and palate at the age of 9-13 years, set by the orthodontist and the oral surgeon. Usually the decisive moment for surgery depends on the developmental stage of the upper canine root.
-taking of lateral cephalometric radiographs, immediately before and after the surgical harvesting/grafting-procedure and three, six, and twelve months postoperatively as is already the protocol.
-assessment of volumetric measurements from lateral cephalometric radiographs.
-statistics.

Intervention

In all participants in this study the bèta-TCP will be used as a filler of the donorsite where the autologous chin bone is harvested.
The outcome of this study will be compared to the results of a retrospective study where Lyostipt(spongegel) was used as a filler of the donorsite.

Study burden and risks

Burden and risks and x-ray diagnostics for this group of test subjects do not differ from standard treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children with cleft of lip, alveolus and palate with radiological proof of half-developmental stage of the root of the upper canine

Exclusion criteria

No cleft of lip and palate
No symphyseal bonegraft

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-02-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	29-05-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL13880.041.06