Bèta-TCP (bèta-tricalcium phosphate) as a bone substitute in patients undergoing repair of the alveolar cleft in CLP(Cleft Lip Palate) patients.

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This current study aims to investigate the use of Curios bèta-TCP, a synthetic tricalcium phosphate for repair of the alveolar cleft in patients with clefts of lip, alveolus and palate.The specific properties of Progentix TCP result in optimal and…

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

Summary

ID

NL-OMON38010

Source
ToetsingOnline

Brief title
Grafting CLP patients with a bone substitute: Bèta-TCP

Condition

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

Synonym
Cleft Lip and Palate (CLP), Harelip

Health condition

cheilognathopalatoschisis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,EU;Seventh Framework Programme;REBORNE-study

Intervention

Keyword: Bèta-TCP, bone substitute, CLP patients, grafting the cleft

Outcome measures

Primary outcome

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

mm) assessed bone volume compared to the original volume of the alveolar cleft.

Secondary outcome

not applicable

Study description

Background summary

At the age of 9-11 years 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 Curios bèta-TCP, a synthetic tricalcium phosphate for repair of the alveolar cleft in patients with 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.
The objectives are:

-Complete closure of the alveolar cleft with bone
-Eruption of teeth as well as guidance by orthodontic interference of these teeth into the newly formed bone must be possible

Study design

-indication for grafting the alveolar cleft in the patient with cleft of lip, alveolus and palate at the age of 9-11 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 3-D CBCT scans with collimator immediately before and after the surgical harvesting/grafting-procedure and six and twelve months postoperatively.
-assessment of volumetric measurements from these scans.
-statistics.

Intervention

In all participants in this study the bèta-TCP will be used as a filler of the prepared recipient site in the alveolar cleft.
The outcome of this study, volumetric bone volume, will be compared to the original volume of the alveolar cleft.
As control group will serve the patient group from Van der Meij's thesis, 2005 Amsterdam, who determined a standard of 70% for bone volume necessity.

Study burden and risks

not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
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 or a viable lateral incisor

Exclusion criteria

No cleft of lip, alveolus and palate.

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):	14-03-2010
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Curios Bèta TCP
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-12-2009
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-06-2012
Application type:	Amendment
Review commission:	METC NedMec

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	NL27084.041.09