Alveolar cleft repair using osteoinductive ceramics in children with unilateral cleft lip and palate

Published: 16-03-2022
Last updated: 04-04-2024

To provide for evidence that calcium phosphate based scaffolds generate equal amounts of residual bone volume compared to the use of autologous bone grafts in unilateral alveolar cleft grafting. A secondary objective is to prove that calcium...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON54352

Source
ToetsingOnline

Brief title
Alveolar cleft repair using osteoinductive ceramics (ACROSTIC)

Condition

- Congenital and hereditary disorders NEC

Synonym
cleft lip and palate, cleft palate

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Financiering door Stichting ter bevordering MKA Chirurgie Utrecht

Intervention

Keyword: Alveolar cleft, Bone substitute, Cleft lip and palate

Outcome measures

Primary outcome

Preoperatively and one year postoperatively routine 3D Cone beam computertomograms are acquired. These are 3D radiological images with significant lower radiation doses than conventional multislice CT scans. Since approximately ten years this is considered as standard of care in all Cleft Units in The Netherlands.

Residual bone volumes are succesively calculated using a voxel based mathching method. (Janssen NG, Schreurs R, Bittermann GKP, Borstlap WA, Koole R, Meijer GJ, et al. A novel semi-automatic segmentation protocol for volumetric assessment of alveolar cleft grafting procedures. J Craniomaxillofac Surg. 2017;45(5):685-9.21.)

Sucessively, residual bone volumes of study and control groups are compared

Secondary outcome

Secondary outcome parameters are eruption of teeth into the recontructed alveolar cleft and pain scores one to seven days postoperatively (based on a ten-point Visual Analog Scale)

Study description

Background summary

At an age of 8 to 12 years, the alveolar cleft is closed in children with cleft lip and palate. An autologous bone graft, mostly harvested from the chin or iliac crest is harvested in order to reconstruct the alveolar cleft defect. This harvesting procedure causes pain at the donor site, inceased operating time and can potentially cause donor site complications. To avoid this the use of a synthetic calcium phosphate bone substitute is a logical next step. Scientific evidence for the effectiveness of calcium phosphate bone sunstitutes in alveolar cleft surgery is currently limited to cohort studies, case series and case reports.

Study objective

To provide for evidence that calcium phosphate based scaffolds generate equal amounts of residual bone volume compared to the use of autologous bone grafts in unilateral alveolar cleft grafting. A secondary objective is to prove that calcium phosphate based scaffolds facilitate canine eruption through the reconstructed alveolar cleft and provide for uncomplicated orthodontic tooth movement in the cleft region.

Study design

A stepped wedge design is applied. There are four participating centers and ech center will switch at a certain time point from their current standard treatment (using autologous bone grafts harvested from the chin) to the use of a calcium phosphate based scaffold (MagnetOs Putty, a CE certified bone substitute for maxillofacial use). The study will not randomise per patient. Daily practise in the UMC Utrecht, where the use of bone substitutes is considered as standard of care, shows that patients with cleft palate and their parents favor the use of a bone substitute. However, thourough scientific evidence for calcium phosphate scaffolds being of equal effectiveness compared to autologous bone grafts for this particular operation is still lacking.

Inclusion will take one year. Goal is to include 30 patients in both study and control group in order to obtain a proper power for a non-inferiority design. Center 1 will start with the study method (use of a bone substitute) after 4 months, center 2 will change from control method to study method after 8 months of inclusion, center 3 will do this after 12 months and center 4 after 16 months. Total inclusion time is 20 months

Intervention

The surgical procedure of alveolar cleft closure is similar in both study and controle group. There only is a difference in the bone transplant that is applied into the reconstructed alveolar cleft:

In the study group: A calcium phosphate based scaffold is placed in the alveolar cleft. It will take approximately one year for the scafflod to be fully replaced by autologous bone.

In the control group: An autologous bone graft, harvested from the patients chin region is used.

Study burden and risks

not applicable

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Cleft lip and palate patients with a unilateral alveolar cleft that are eligible for early secondary alveolar closure. Timing of surgery and therefore inclusion is based on the moment of eruption of teeth into the alveolar cleft and usually correlates with a calendar age of 8 to 12 years

Exclusion criteria

Patients for which the time frame of early secondary alveolar closure has passed
Patients with a (craniofacial) syndrome
Patients with bilateral alveolar clefts
Patients with intellectual disability

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-05-2022
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	MagnetOs Putty
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-03-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	19-04-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-06-2023
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	NL75562.041.21