Treatment Effect of Bone Anchored Protraction in Cleft Patients

Published: 04-07-2017
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Bone-anchored maxillary protraction therapy improves facial profile in cleft children.

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

Summary

ID

NL-OMON23018

Source
Nationaal Trial Register

Brief title
N/A

Condition

- Congenital and hereditary disorders NEC

Synonym
Cleft

Health condition

Subjects born with cleft lip and or palate, but with good general health.

Research involving
Human

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: N/A

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

3D changes in craniofacial hard tissues and facial soft tissues

Secondary outcome

Corelation and ratios between the changes in hard and soft tissues; Predictive values of patient-related factors in treatment outcomes; Patient perception and experience in BAMP therapy

Study description

Background summary

All patients with isolated, unilateral complete cleft lip and palate between 10-12 years were included. All patients have been under treatment by one orthodontist at the Department of Orthodontics of University Medical Center Groningen, the Netherlands and have undergone a series of interdisciplinary treatments within the same medical center.

Study objective

Bone-anchored maxillary protraction therapy improves facial profile in cleft children.

Study design

1.5 year follow up, 3.5 year follow up and 5 year follow up

Intervention

Effect of wearing intermaxillary elastics on bone anchors on facial growth and esthetics.

Contacts

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Eligibility criteria

Age
Children (2-11 years)
Children (2-11 years)
Adolescents (12-15 years)
Adolescents (12-15 years)
Adolescents (16-17 years)
Adolescents (16-17 years)
Adults (18-64 years)
Adults (18-64 years)

Inclusion criteria

- Cleft subjects aged at 10-12 at the start of treatment with mild to moderate Class III malocclusion

Exclusion criteria

- Class I or Class II malocclusion

- Subjects with severe Class III malocclusion, other serious medical conditions or stopped treatment because of moving or other unexpected reasons.

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2015
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	04-07-2017
Application type:	First submission
Review commission:	nWMO adviescommissie UMC Groningen

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
NTR-new	NL6375
NTR-old	NTR6559
Other	UMCG : METc 2017/318

Study results

Summary results
N/A