Quantitative and functional echographic assessment of reconstructed schisis (cleft lip)

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Objective 1: To determine the differences in composition of tissues and function of the upper lip between reconstructed cleft lip patients and healthy subjects.Objective 2: To test the possibility to detect anatomical and functional differences...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON31074

Source
ToetsingOnline

Brief title
Echographic assessment of schisis

Condition

- Other condition

Synonym
cleft lip

Health condition

schisis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cleft lip, Echography, Reconstruction, Schisis

Outcome measures

Primary outcome

Ultrasound data of the upper lip will be collected and 3D facial photographs

will be made. These are both non invasive methods with no potential adverse

affects

Secondary outcome

None

Study description

Background summary

When children with a cleft lip are born a recontruction has to be performed in which the continuity of the m.orbicularis oris has to be restored. After the surgical intervention the amount of scar tissue and its position have functional and esthetic consequences. Although the esthetic outcome of an intervention might clinically assessed, it remains unclear to what extend the continuity and the functionality of the muscle have been established. For this reason, it is important to investigate the anatomy of the reconstructed lip. Moreover, it is unknown to what extend scartissue has an effect on muscle function. By making detailed anatomical information available, it might be possible to better evaluate the outcome of treatment. It is also of importance to quantify the contractive performance of the involved muscle in order to give the surgeon feed-back To achieve a refinement of the reconstructed method and to support decision making of further therapy. Two techniques have been developed to determine the anatomical and functional characteristics of the m. orbicularis oris by means of ultrasonography (or echography). Characteristics of the ultrasound images are being quantified to determine the composition of tissues. A technique called elastography has been developed to quantify and

visualize the deformation of tissues during function. We hypothesize that scar tissue can be differentiated from healthy tissue by relative echo level and that scar tissue shows no active deformation during functional movement while normal tissue shows up to 25% of deformation with SD of 5-10%.

Study objective

Objective 1: To determine the differences in composition of tissues and function of the upper lip between reconstructed cleft lip patients and healthy subjects.

Objective 2: To test the possibility to detect anatomical and functional differences prior to and after final reconstructive lip surgery in cleft patients.

Study design

First part of the study:
Case-control study
Duration and setting: The subjects will be asked to make one appointment of 30 minutes for collection of ultrasound data at the out-patients clinic of the department of Pediatrics Radboud University Nijmegen Medical Centre and to make 3D facial photographs at the out-patients clinic of the department of Maxillofacial Surgery Radboud University Nijmegen Medical Centre.

Second part of the study:
Cohort study
Duration and setting:
-One appointment of 30 minutes is made with patients one week prior to the final reconstructive lip surgery to collect ultrasound data and to make facial photographs.
-Four appointments of 30 minutes are made with subjects ten days, one month, 3 months and six months after surgery to collect ultrasound data and to make 3D facial photographs
All appointments are held at the out-patients clinic of the department of Pediatrics Radboud University Nijmegen Medical Centre.

Study burden and risks

No burden except time. No risks

Contacts

Public

Universitair Medisch Centrum Sint Radboud

Phillips van Leijdenlaan 25
6500HB Nijmegen, Pb 9101
Nederland

Scientific

Universitair Medisch Centrum Sint Radboud

Phillips van Leijdenlaan 25
6500HB Nijmegen, Pb 9101
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Caucasian
Unilateral Cleft Lip
Patients treated from birth in the Cleft Palate Craniofacial Unit, Radboud University Nijmegen Medical Centre

Exclusion criteria

Other than Caucasian persons
Bilateral and incomplete clefts
Other congenital anomalies present
Patients underwent lipclosure elswhere

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL17676.091.07