Cine-MRI to diagnose glossoptosis in Robin Sequence (RS)

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Aim of total study:Diagnosing all components of RS in an objective mannerAim of present substudy:Increasing the reliability and decreasing the burden of the method with which glossoptosis can be determined in newborns with RS

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON40786

Source
ToetsingOnline

Brief title
Cine-MRI to diagnose glossoptosis in RS

Condition

- Respiratory disorders congenital
- Neonatal respiratory disorders

Synonym
Glossoptosis, Upper airway obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Legaat (via Nederlandse Vereniging van Plastische Chirurgie)

Intervention

Keyword: Cine-MRI, Glossoptosis, Robin, Sequence

Outcome measures

Primary outcome

1. Feasibility Cine MRI

2. Accuracy of Cine MRI in showing upper airway obstruction/glossoptosis

Secondary outcome

not applicable

Study description

Background summary

Robin Sequence (RS) is an infrequent condition characterized by micrognathia and respiratory insufficiency, with or without cleft palate. RS is clinically characterized by varying degrees of upper airway obstruction, which is often caused by glossoptosis, leading to respiratory insufficiency and feeding difficulties. Many researchers therefore add glossoptosis as essential component of RS.
In literature no consensus exists regarding the criteria to define RS. Studies describing the various management strategies use different definitions, severely impairing meta-analysis. Further etiological studies or management trials can only be performed if a single, strict definition with objective criteria for RS is available. Micrognathia can be studied using 3D facial scanning, and respiratory problems through polysomnographies. For glossoptosis no such relatively simple diagnostic tool is available. We hypothesize that Cine MRI will be a useful method in objectifying glossoptosis, and be more patient friendly than the currently used gold standard, flexible fiberoptic laryngoscopic visualization by the ENT surgeon.

Study objective

Aim of total study:
Diagnosing all components of RS in an objective manner

Aim of present substudy:
Increasing the reliability and decreasing the burden of the method with which

glossoptosis can be determined in newborns with RS

Study design

Observational study with noninvasive measurements.

Study burden and risks

The risk of Cine MRI is limited. No anesthesia will be needed by using the *Feed and wrap* method. There is no benefit for the participants (patients; control group) to the study. There may be a group benefit for patients who will be diagnosed with RS in the future as the diagnosis may be confirmed more easily. Having a strict definition with objective measurements will be essential for research and optimal treatment. For the control group the burden will be very limited since the scanning time will increase 3-5 min compared to the time for their brain MRI for patient care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Patient group:
• Subjective diagnosis of Robin Sequence:
• Micrognathia, diagnosed by the responsible physician
• Upper airway obstruction diagnosed with polysomnography
• With or without cleft palate
• Informed consent by parents / caregivers;Control group:
• Neonate of 0-2weeks undergoing a brain MRI for patient care purposes
• No known congenital anomalies
• Informed consent signed

Exclusion criteria

Patients/controls and their parents unable to read and understand the written information

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO Date:	19-11-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL49007.018.14