The use of MRI-scans to assess velopharyngeal insufficiency in cleft palate patients

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The key objective of this study is to determine the clinical significance of using MRI scans as a diagnostic tool to assess velopharyngeal insufficiency in cleft palate patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON56871

Source
ToetsingOnline

Brief title
The use of MRI-scans to assess VPI

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
Velopharyngeal insufficiency; hypernasal speech

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cleft palate, MRI, Velopharyngeal insufficiency

Outcome measures

Primary outcome

Differences in MRI-measured parameters of velopharyngeal anatomy between patients with cleft palate and VPI, and individuals with cleft palate without VPI. Differences in MRI-measured parameters of velopharyngeal anatomy between patients in which speech therapy/surgical treatment is/is not successful, and individuals with cleft palate without VPI.

Secondary outcome

Secondary study parameters include the same research questions as described with regard to MRI measured parameters on velopharyngeal anatomy, applied to nasometry, speech test, nasendoscopy, oral inspection and PROMs outcomes.

Study description

Background summary

20-30% of children with a history of cleft palate repair develop velopharyngeal insufficiency (VPI). VPI is defined as inadequate closure of the soft palate to the posterior pharyngeal wall, resulting in hypernasality, nasal air emission and reduced speech loudness. The current golden standard in The Netherlands for assessment of VPI consists of speech tests and nasoendoscopy. However, these diagnostic tools mainly provide subjective information on velar anatomy and function. It does not allow for assessment of the position and function of the velar muscles, which have a large effect on velar function and therefore on speech. In the literature, magnetic resonance imaging (MRI) has been proposed for direct evaluation of the gap size between the soft palate and the posterior pharyngeal wall, velar mobility and the location of the velar muscles that play a role in VPI. MRI is non-invasive and free of radiation exposure. Furthermore, it has proven to be a child-friendly, reproducible, and repeatable method providing a three-dimensional view of the velopharyngeal structures and

function during speech4 and is currently used in numerous cleft units in the United States. We believe that implementing MRI-scans in our standard care will improve health care for children with VPI and could influence our cleft palate surgery technique.

Study objective

The key objective of this study is to determine the clinical significance of using MRI scans as a diagnostic tool to assess velopharyngeal insufficiency in cleft palate patients.

Study design

Monocenter, prospective cohort study.

Study burden and risks

The standard care consists of visits to the outpatient clinic, speech and language tests and nasoendoscopy. In this study, the participants will have to fill out two short surveys and visit the outpatient clinic one extra time in order to have the MRI scan. The risk of physical harm in unsedated MRI is very low6, and unsedated MRI without contrast agents in paediatrics meets the minimal-risk standard. In paediatric populations, the risk of considerable fear and discomfort with regard to an MRI scan is also low6. Furthermore, in case of anxiety, and aged under six years, children will be referred in order to receive additional child-friendly explanation and preparation prior to the scan. The additional information obtained with the MRI scans could lead to improved diagnosis and treatment of VPI amongst the study population. VPI is usually diagnosed and treated at the age of 4-9 years. Treatment is of great importance due to the substantial morbidity and developmental delay VPI could cause due to impairment of the child*s ability to communicate in both social and educational settings. Therefore, clinically significant VPI is extremely rare amongst adults and this study will have to be carried out with minors.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific

Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

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)

Inclusion criteria

- >4 years of age
- History of non-syndromic unilateral cleft lip and palate (UCLP)
- History of cleft palate repair (Von Langenbeck technique)
- No history of secondary palate surgery
- Hypernasality
- Informed consent
- Patient <12 years of age: informed consent required from parent(s)/legal guardian(s)
- Patients 12-16 years of age: informed consent required from both patient and parent(s)/legal guardian(s)
- Patient >16 years of age: informed consent required from patient
- Patient can be well instructed with regard to the MRI scan

Exclusion criteria

- <4 years of age
- Syndromes
- No history of UCLP
- Primary cleft palate repair with other technique than Von Langenbeck

- History of secondary palate surgery
- No hypernasality
- No informed consent
- Non removable orthodontic device
- Patient cannot be well instructed with regard to the MRI scan
- Any exclusion criteria regarding the MRI scan

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:	Pending
Start date (anticipated):	02-09-2024
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-06-2024
Application type:	First submission
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	NL86277.018.24