Language representation in children with 22q11 deletion syndrome and children with Specific Language Impairment

Published: 28-09-2017
Last updated: 04-01-2025

The main objective of this study is to determine the language representation in the brain of children with SLI and 22q11DS.

Ethical review	Approved WMO
Status	Completed
Health condition type	Mental impairment disorders
Study type	Observational invasive

Summary

ID

NL-OMON44550

Source
ToetsingOnline

Brief title
Language representation in 22q11 and SLI

Condition

- Mental impairment disorders

Synonym
Language development problems

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 22q11DS, fMRI, Language, Specific Language Impairment

Outcome measures

Primary outcome

Similarity between 22q11DS and SLI language activation patterns and that of a healthy control population. In other words: do the children with 22Q11DS and SLI show fMRI language-activation in the same brain regions as controls?

Secondary outcome

Correlation between language activation parameters (e.g. language lateralization index, amplitude of signal changes in the language areas) and scores on language tasks of the children with language impairment.

Study description

Background summary

Developmental language impairments have a profound impact on an individual's life. About 7% of children show severe and persistent delays in the development of primary language skills (speaking and/or understanding) without any obvious neurological, psychological or social causes. This condition is called specific language impairment (SLI). The etiological heterogeneity of SLI currently hampers our ability to advance the understanding of the trajectory from cause to the neurocognitive deficits that ultimately lead to the abnormalities of language (acquisition) that warrant a diagnosis of SLI. To overcome this obstacle, a larger project by Prof. Frank Wijnen (*Language impairment in the 22q11.2 deletion syndrome: a model for SLI?*), aims to study a developmental language disorder that overlaps phenotypically with SLI but has a uniform genetic etiology: the 22q11.2 deletion syndrome (22q11DS). In a subproject, we here aim to determine the language representation in the brains of children with SLI and 22q11DS, in order to obtain an indepth insight into the language development of both these groups, and relate behavioural and neuropsychological information to information about language brain function and how the brain processes language. The outcome of this study will not only shed light on the usability of 22Q11DS as a model for SLI, but will also increase our

understanding of the underlying causes of these language development disorders at the level of the brain.*

Study objective

The main objective of this study is to determine the language representation in the brain of children with SLI and 22q11DS.

Study design

Observational study

Study burden and risks

No direct benefits are expected for the subjects of the current study, but the study is expected to increase our understanding of problematic language development, which, in the long run, will contribute to adequate treatment. There are no known risks associated with performing a tone-audiogram, language tests or with fMRI acquisition and the risks of participating in the study are therefore considered negligible. fMRI does not require administration of any contrast agent or ionizing radiation. The UMC Utrecht has ample experience in performing fMRI scans with (young) children. In a currently running fMRI study for example (ethics protocol 16-373), we are successfully performing fMRI scans with healthy children and children with epilepsy between 6 and 10 years old. The scanner is handled by trained personnel and subjects are screened for metal before entering the scanner.
Besides the risk, also the burden of participating in the study can be considered negligible. Performing the language tasks may be somewhat tiring for the participants, but included subjects will be relatively familiar with the concept of doing language tasks since they have a diagnosis with a language disorder, and as such, the tests will not pose a large burden on them. If necessary, participants can take a pause between language tasks. Concerning the fMRI scan: first, the fMRI procedure is painless, although slight discomfort may occur due to lying still with the head and part of the body confined in a tunnel-like device. Second, the fMRI tasks are much like computer games or watching videos for children, and as such pose a minimal burden. Third, for all children it will be considered to perform a practice scanning session in a *mock-scanner* before the actual scan, in order to familiarize them with the MRI setting (see Standard Operating Procedure Section 15) and practice the tasks. When, during or after this practice session, it becomes clear that a participant strongly dislikes the procedure, or considers the procedure scary, the participant will be excluded from the study and no real MRI session will be done. The decision to perform a mock-scan or not will be made in consultation with the participant and his/her parents. Further measures taken to minimize the burden are: If a subject experiences claustrophobia during scanning, or is uncomfortable with any aspect of the procedure and wants to quit, the session

will be terminated. During scanning, the subjects are provided with earplugs and/or headphones to protect them from scanner noise. Upon request, one of the parents/caretakers is allowed to remain in the scanner room, close to the subject. An intercom is available in the scanner to remain in contact with the subject and the parent/caretaker during the whole session and an emergency button is placed with the subject or parent/caretaker, with which he/she can indicate to stop the procedure immediately.

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
Children (2-11 years)

Inclusion criteria

- Age 6-10 years old
- A diagnosis of Specific Language Impairment (SLI) or 22q11DS

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Metal objects in the body that are not MRI compatible
- Anxiety in the scanner (evaluated by parent/caretaker, or after practice in mock scanner)
- Both verbal and non-verbal IQ lower than 70
- Severe hearing loss (>35 dB)
- Relevant comorbidities (i.e. severe autism)
Notably, to determine the last three parameters, the respective physician/hospital or school/institution will be asked to provide the researchers with neuropsychological/IQ test results, the results of hearing tests and relevant comorbidities. Parents/caretakers of participants will be asked for permission for this during one of the phone calls in the recruitment phase. To confirm current hearing ability, during the first visit, a tone audiogram will be made. If a recent (i.e. less than 2 years old) IQ test is not available, a new IQ test will be administered.

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	22-01-2018
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	28-09-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-11-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL62366.041.17

Study results

Date completed:	08-07-2018
Results posted:	19-08-2021

First publication
01-01-1900