Functional and structural brain problems underlying language development disorders in preterm children followed up at age 9

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(1) Longitudinally describe the language and speech development in preterm children at 9 years of age. (2) Investigate whether these outcomes are related to a divergent development of neurological (language) system and (3) whether these language and...

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

Summary

ID

NL-OMON46275

Source
ToetsingOnline

Brief title
Brain problems in preterm children with language development disorders.

Condition

- Other condition
- Neonatal and perinatal conditions

Synonym
communication disorder, language development disorders

Health condition

language and speech development

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Not clear yet;we are writing an application to get a grant in the near future.

Intervention

Keyword: Brain problems, Language development, Prematurity

Outcome measures

Primary outcome

The main outcome measure is the Core language score measured by the Clinical Evaluation of Language Fundamentals-4 (CELF).

Secondary outcome

The secondary outcome measures are: receptive vocabulary (Peabody Picture Vocabulary Test * PPVT); narrative ability (Renfrew Bus-story), functional brain synchronisation (EERG/ERP), academic achievement (Cito-scores), intelligence quotient (Wechsler Intelligence scale for children), complex hearing (DDT), behaviour (Child Behaviour Checklist * CBCL), executive functions (Behaviour Rating Inventory of Executive Function * BRIEF), the competence experience of the child (Competence Experience Scale for Children * CESC), intelligibility (Intelligibility in Context Scale * ICS), parent*s satisfaction with the child*s communication in every-day communication (VAS-scale and Children*s Communication Checklist - CCC-2); receptive vocabulary of one of the parents (Peabody Picture Vocabulary Test * PPVT) and quantifiable microstructural connectivity of both brain hemispheres using

advanced Magnetic Resonance Imaging (MRI) scan sequences (so called diffusion

tensor imaging sequences).

Study description

Background summary

Nowadays, one in ten children is born prematurely, which amounts to approximately 500,000 preterm infants in Europe each year. Approximately 40% of infants born at 24-32 weeks* gestational age show neurodevelopmental problems, including problems in speech and language functions. Problems with complex language functions seem to increase between the age of 3 to 13 years of age. Since language is extremely important to academic achievement and communication in everyday life, these results are important and alarming. The underlying neural causes for these language problems are still not clear! Why does language develop well in some ex-preterms, but not in others? Although neuroimaging studies have shown some general structural and functional differences in preterm compared to term-born children, longitudinal outcome studies of (complex) language functions are lacking in this important patient group. Knowledge is needed to understand the effects of preterm birth on long-term language development.

Study objective

(1) Longitudinally describe the language and speech development in preterm children at 9 years of age.
(2) Investigate whether these outcomes are related to a divergent development of neurological (language) system and
(3) whether these language and neurological outcomes within the preterm-born group somewhere along the trajectory (at age 2, 4 or 9 years) can predict problems in academic achievement.

Study design

This study is a follow-up of the longitudinal cohort study of van Noort-van der Spek [MEC-2012-149] and contains a single-centre longitudinal observational cohort. 62 patients of the original study population of van Noort-van der Spek were assessed at the age of 2 and 4 years of age and gave permission to contact them for follow-up academic research. The primary caregivers will be invited to participate in the recent study after informed consent. Parents and children can participate by completing several questionnaires regarding behaviour, executive functions, self-perception of the child, intelligibility and communication in general. They will be asked to visit Erasmus MC-Sophia to test

simple and complex language and speech functions, peripheral and complex hearing functions, brain activity and cognitive function. One of the parants will be asked to do a receptive vocabulary test. The child*s teacher will be asked to complete questionnaires concerning behaviour and executive functions and provide scores of academic achievement (Cito-scores). After this visit parents and child will be asked to participate in an optional additional second visit to make a structural (advanced) MRI-scan of the brain of the child.
A group of matched term-born children will participate in only a subset of the tests: ERP, hearing test, word comprehension test.

Study burden and risks

Burden for preterm children: The child*s behaviour, executive functions, intelligibility and self-judgement is assessed by questionnaires for parents (total of 45 minutes), teacher (total of 35 minutes) and/or the child itself (15 minutes). In a first visit to the Erasmus MC-Sophia the complex language function will be determined in approximately 90 minutes. ERP will be measured by wearing an electrode cap (60 minutes). After lunch the IQ (60 minutes) and hearing function (20 minutes) will be measured. During the IQ-test, the parent will be doing the short receptive vocabulary test. In an optional second visit a MRI-scan will be made (60 minutes).

Burden for term-born children: word comprehension test (10 minutes), ERP-measurement (60 minutes), hearing test (20 minutes).

Burden participating parents of preterm-born children: word comprehension test (10 minutes), the assessment will take place at the same time the child is doing the IQ-test with the psychologist. This way, it will not cost the parent and child extra time in the hospital.

Benefit and Risks: Collecting cognitive, language, speech and hearing scores does not include any risks. Wearing the electrode cap for the purpose of EEG/ERP neither includes any risks. The optional MRI-scan is also considered very safe, since all standard procedures will be followed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

For preterm subjects (N<=60): Children and their parents participated in the study by van Noort-van der Spek [MEC-2012-149], and parents gave permission to contact them in the future for scientific research, in their last contact moment.
One parent of each participating preterm child (N<=50): the parent that is accompanying the child at the day of testing has to give permission to participate in a language subtest himself/herself.;For term-born control children (N<=24): Children must be born at term age (>37 weeks of gestation) and an individual child must be matched to one of the preterm subjects with in respect to age, gender and education level of the mother.

Exclusion criteria

Participants (preterm-born and term-born) with a permanent (sensorineural) hearing loss from >20 dB at the best ear, measured with pure tone audiometry, will be excluded from participation.;Exclusion criteria for making the MRI scan in the optional additional visit are:
(1) Non-removable non-MRI compatible implants;
(2) Claustrophobia

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:	Recruitment stopped
Start date (anticipated):	14-11-2016
Enrollment:	134
Type:	Actual

Ethics review

Approved WMO Date:	20-01-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-03-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-06-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-12-2017

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL54905.078.15