

# Speech and language development in very preterm children

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Primary objectives: (1) To longitudinally describe the speech and language development in VPT children at 2 and 4 years of age, and (2) to identify possible neonatal and personal risk factors associated with speech and language impairment in 4-year-...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON56937

### Source

ToetsingOnline

### Brief title

Speech and language development in very preterm children

### Condition

- Other condition

### Synonym

language disorder, speech disorder

### Health condition

spraak- en taalontwikkeling, vroeggeboorte

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Erasmus Medical University Center Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** language development, speech development, very preterm children

## Outcome measures

### Primary outcome

A measure of language function in terms of sentence quotient (SQ) and a measure of speech function in terms of percentage of correct consonants (PCC) at 4 years of age.

### Secondary outcome

Additional language parameters: Measures of other domains of language function, i.e. lexicon (word quotient, WQ) and phonological awareness (pseudoword quotient, PWQ) assessed at 4 years of age.

## Study description

### Background summary

In the Netherlands about 2 to 3 percent of children are born VPT (i.e. GA <32 weeks or BW <1500 grams). Meta-analyses highlighted substantial impairment in multiple developmental domains in preterm children throughout childhood, such as cognitive and motor development, language development, behavior, and academic achievement (Van Noort-van der Spek et al, 2012; Wolke et al, 1999; Bhutta et al, 2002; Kieviet de et al, 2009; Aarnoudse-Moens et al, 2009). Even with no major neurosensory impairment (i.e. cerebral palsy, mental developmental index <70, or severe visus and hearing impairment) approximately 20-40% of VPT children develop speech and languages problems (Wolke et al, 1999). 24% of VPT children has no normal speech by age 6 (Wolke et al, 1999). In spite of the large amount of research conducted on speech and language function in very preterm children, little is known about the risk factors which are associated with speech and language impairment in VPT children entering

primary school. An adequate speech and language development is extremely important in the light of a child's learning and social-emotional development. Hille et al found that at the age of 9 years, 19% of VPT children were in special education compared to 4.7% in the general population. Of the VPT children in mainstream education, 32% were in a grade below appropriate level for age and 38% had special assistance (Hille et al. 2007). Since language function is essential in all kinds of social and academic life, insight in the developmental course of speech and language function and the possible risk factors for speech and language impairment is of great value. Timely and appropriate intervention of speech and language problems in this vulnerable population may prevent emotional, social, and learning deficits, and may improve long-term outcomes, reducing the need for special education (Beitchman et al, 1996; Agt van der et al, 2007).

### **Study objective**

Primary objectives: (1) To longitudinally describe the speech and language development in VPT children at 2 and 4 years of age, and (2) to identify possible neonatal and personal risk factors associated with speech and language impairment in 4-year-old VPT children entering primary school.

Secondary objective: To examine the association between speech and language problems and cognitive development, behavior and hearing function in VPT children at 2 and 4 years of age.

### **Study design**

A single-center, prospective, cohort study in which VPT infants will be assessed with well-known and standardized speech, language, and hearing tests at 4 years of age.

### **Study burden and risks**

Burden:

Determination of speech, language, and hearing function requires an hospital visit at the age of 4 years. This visit will last at the most 1 hour and 20 minutes in total.

Benefit and risks:

The 100 VPT children will be assessed with well-known and standardized speech, language and hearing tests, of which in literature and clinical practice no risks are known.

Group relatedness:

VPT children are at risk for substantial impairment in multiple developmental domains throughout childhood, such as cognitive and motor development, language development, behavior, and academic achievement.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Children (2-11 years)

### **Inclusion criteria**

Birth weight <1500 grams, gestational age <32 weeks, single birth, Dutch speaking family background.

### **Exclusion criteria**

Severe sensory problems (e.g. blindness or deafness), oral structure deficits (e.g. cleft palate), chromosomal abnormalities.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 20-06-2012

Enrollment: 100

Type: Actual

## Ethics review

Approved WMO

Date: 20-06-2012

Application type: First submission

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	NL40006.078.12