

Intervention and Development at 5 and 6 years after premature birth

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1. To assess the policy on referral to and use of special outpatient services at 6 years after very preterm birth. 2. To examine whether use of special outpatient services is associated with progress in physical, cognitive, neuromotor, and behavioral...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON36987

Source

ToetsingOnline

Brief title

I-ON Preterm

Condition

- Neonatal and perinatal conditions
- Cognitive and attention disorders and disturbances

Synonym

developmental problems, preterm birth

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Aanvraag is ingediend

Intervention

Keyword: Developmental problems, Early school age, Preterm

Outcome measures

Primary outcome

Physical and neuromotor development:

- * Growth and wellbeing
- * Neurological development (Touwen Neurological Assessment)
- * Motor development (Movement Assessment Battery for Children-II-NL)

Cognitive development:

- * Cognitive development (Wechsler Preschool and Primary Scale for Intelligence-iii-NL[WPPSI-iii-NL])
- * Executive function (Stop Signal task, visual working memory, verbal working memory tasks)
- * Visual-motor integration (Beery VMI en tracking task)
- * Language (Receptive Language en Names Pictures WPPSI-iii-NL)

Academic achievement functioneren

- * CITO Pupil Monitoring System

Behavior

- * Child Behavior Checklist 1.5-5 years en 6-18 years [CBCL\1.5-5][CBCL\6-18];
- * Teacher Report Form 1.5-5 years en 6-18 years [TRF\1.5-5][TRF\6-18];
- * Behavior Rating Inventory Executive Function (BRIEF);

* Vragenlijst Sociale Communicatie (SCQ);

* Gedragsvragenlijst voor Kleuters[GvK]

Secondary outcome

Use of special outpatient services at 5 and 6 years after very preterm birth.

Study description

Background summary

In the Netherlands, about 2200 children are born very preterm (gestational age < 30 weken) or with very low birthweight (birthweight < 1000 grams). Preterm children are at risk for developmental problems. 15% of these children has a severe disability. However, the majority of the children without a severe disability is still at risk for developmental problems in the cognitive, neuromotor, or behavioral domain. Most of these problems become apparent at early school age, at 5 years.

To detect such developmental problems and timely refer for treatment, the development of very preterm children is standard monitored at the Neonatology outpatient clinic of the AMC. After a thorough examination of the physical, cognitive, neuromotor, and behavioral development of the child, a majority of the children is referred for special outpatient services, such as physical therapy, occupational therapy, speech therapy, etc. Involved costs are high, but the extent of special outpatient care needed for this population has for the Dutch situation, never been examined. It is also unknown to what extent referral to such special services meets parental satisfaction and contributes to a better development of very preterm children.

This study will examine the current referral policy after the standard examinations at 5 years of age in very preterm children and will also examine effects of the referral policy on developmental outcomes at 6 years of age.

Study objective

1. To assess the policy on referral to and use of special outpatient services at 6 years after very preterm birth.
2. To examine whether use of special outpatient services is associated with progress in physical, cognitive, neuromotor, and behavioral development at 6 years in very preterm children.

Study design

Follow-up study in very preterm children at 6 years of age and a term reference group of comparable age and sex.

Study burden and risks

None.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Children born < 30 weeks of gestation and/or birthweight < 1000 grams admitted to the Neonatal Intensive Care Unit AMC and included in our local Neonatal Follow-up Program

conform National Guidelines.

Exclusion criteria

None.

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):	08-01-2013
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO	
Date:	08-01-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	17-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date: 19-09-2014
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	NL42074.018.12