

# Preterm INfants KnowLegde on Target height and outcomE.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27888

### Source

NTR

### Brief title

Pinkeltje

### Health condition

Preterms; born before 36 weeks completed weeks of gestation in 2002 or 2003, and in care of a well child health centre participating in the study.

Controls; children born between 38 and 41+6 weeks of gestation in 2002 and 2003 cared for by the same participating child health centres.

## Sponsors and support

**Primary sponsor:** Friesland foods

Abbott

## Intervention

## Outcome measures

### Primary outcome

Neurodevelopment and growth.

### Secondary outcome

N/A

## Study description

### Background summary

Preterm infants born before 32 weeks of gestation are called high risk preterm infants (HRPI) and are known to be at high risk for growth and neuro-developmental disorders. Adequate catch up growth has a beneficial effect on developmental outcome. "Too much" catch up growth might lead to an increased risk for developing the metabolic syndrome. Perinatal risk factors that influence neurodevelopmental outcome in HRPI have been studied extensively.

Low risk preterm infants (LRPI) born between 32 and 36 weeks of gestation have not been studied extensively, but a subgroup of these LRPI might be at an increased risk of developing growth and neurodevelopmental disorders as well. Which perinatal risk factors influence the neurodevelopmental outcome and growth of LRPI is not known.

We will assess perinatal and postnatal risk factors, (including pregnancy and medication mother) growth parameters and neurodevelopmental outcome in HRPI and LRPI compared to controls.

We will also study the efficacy of a modified version of the Dutch Van Wiechen Developmental screenings test to identify preterm infants at a young age who are at high risk of neurodevelopmental problems at school age.

## Study objective

Growth and development of high risk and low risk preterm infants differ from children born at a normal gestational age. Perinatal riskfactors, development and growth of high risk and low risk preterm infants are different.

## Study design

N/A

## Intervention

1. Measurement of growth parameters at the age of 3 years and nine months;
2. Retrospective analysis medical records mother and child;
3. Questionnaires on development, behaviour socio-economic and medical conditions at 3 year and nine months and at the age of 5 years;
4. WISC-R intelligence test and movement ABC test between the age of 6 and 7 years.

## Contacts

### Public

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## Eligibility criteria

## Inclusion criteria

All infants born before 36 completed weeks gestation in a well defined large region of the Netherlands in 2002 and 2003.

## Exclusion criteria

1. Major congenital malformations;
2. congenital infections.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2005
Enrollment:	2125
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	28-07-2006
Application type:	First submission

## 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
NTR-new	NL729
NTR-old	NTR739
Other	: N/A
ISRCTN	ISRCTN80622320

## Study results

### Summary results

N/A