

Preterm infants knowledge on target height and outcome

Submission date 28/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/12/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.pinkeltje-onderzoek.nl>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Preterm infants knowledge on target height and outcome

Acronym

PINKELTJE

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethical Review board of the University Medical Centre Groningen, 02/09/2005, ref: 130-2005

Study design

Observational prospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Low birth weight Infants

Interventions

In this observational, cohort study, there are no interventions; the following measurements will be made:

1. Measurement of growth parameters at the age of three years and nine months
2. Retrospective analysis medical records mother and child
3. Questionnaires on development , behaviour socio-economic and medical conditions at three years and nine months and at the age of five years
4. Wechsler Intelligence Scale for Children-Revised (WISC-R) intelligence test and movement Assessment Battery for Children (ABC) test between the age of six and seven years

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Neurodevelopment and growth

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/10/2005

Completion date

31/12/2010

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

2125

Key exclusion criteria

1. Major congenital malformations
2. Congenital infections

Date of first enrolment

01/10/2005

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Groningen

Groningen

Netherlands

9700 RB

Sponsor information

Organisation

University Medical Center Groningen (UMCG) (The Netherlands)

Sponsor details

Beatrix Children's Hospital

PO Box 30001

Groningen

Netherlands

9700 RB

Sponsor type

Hospital/treatment centre

Website

<http://www.rug.nl/umcg/index?lang=en>

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Research organisation

Funder Name

Friesland Foods Units Western Europe and Enhanced Nutrition and Research (ENSU) (The Netherlands)

Funder Name

Abbott (The Netherlands)

Funder Name

Cornelia Foundation for the Mentally Handicapped Child (USA)

Funder Name

Stichting Vrienden Beatrix Kinderziekenhuis

Alternative Name(s)

Research Foundation of the Beatrix Children's Hospital, Stichting Beatrix Kinderziekenhuis

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Funder Name

Anneke Bulk General Child Health Care Research Fund (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	developmental delay results	01/07/2011		Yes	No
Results article	behavioural and emotional problems results	01/02/2012		Yes	No
Results article	demographics results	01/08/2012		Yes	No
Results article	neonatal morbidity results	01/08/2012		Yes	No
Results article	neuropsychological functioning results	01/10/2012		Yes	No
Results article	developmental delay results	01/12/2012		Yes	No
Results article	respiratory problems results	01/06/2013		Yes	No
Results article	low socioeconomic status results	01/11/2013		Yes	No
Results article	RSV infection results	01/04/2015		Yes	No
Results article	gross motor milestones results	01/04/2018		Yes	No
Results article	results	01/12/2018		Yes	No
Results article	results	02/05/2019	15/01/2020	Yes	No
Results article	results	17/02/2021	26/02/2021	Yes	No
Results article		17/03/2021	15/12/2021	Yes	No