

The effects of birth after 32-36 weeks of pregnancy on the lung function of children at the age of 12

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The hypothesis is that moderate and late preterm infants at age 12 reported more symptoms consistent with asthma and use more asthma medications, as well as a poorer lung function, exercise capacity and Lung Clearance Index than healthy peers.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26209

Bron

Nationaal Trial Register

Verkorte titel

Follow up study PINKELTJE-cohort

Aandoening

Preterm birth (prematuriteit)

Asthma (astma)

Lung function (longfunctie)

Exercise capacity (inspanningscapaciteit)

Lung Clearance Index (LCI)

Ondersteuning

Primaire sponsor: UMCG

Overige ondersteuning: SAB (Stichting Astma Bestrijding)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Spirometrie : FVC, FEV1, FEV1/FVC, FEF25, FEF50, FEF75, PEF

Ergometrie : Hartfrequentie, ademhalingsfrequentie, maximalebelasting, VO2rust, maximale ademfrequentie, VT, VTmax, VEmax, ventilatoire reserve, VO2 op de anaerobe drempel (AD), VO2max, AD, AD/VO2, ΔVO2/ΔWR, respiratory exchange ratio, Borg score

LCI : LCI, Scon, Salv

Toelichting onderzoek

Achtergrond van het onderzoek

There has been much research into lung problems in extremely preterm children. A "forgotten group" is the group of children born between 32 and 36 weeks gestation. Research shows that at age 5, these children do indeed have respiratory symptoms, and report a doctor's diagnosis of asthma more often. This study is to determine how these children are at the age of 12 in the respiratory field. To investigate this, we use questionnaires, LCI, spirometry and exercise testing.

Doel van het onderzoek

The hypothesis is that moderate and late preterm infants at age 12 reported more symptoms consistent with asthma and use more asthma medications, as well as a poorer lung function, exercise capacity and Lung Clearance Index than healthy peers.

Onderzoeksopzet

March 2014: authorization procedure Metc

September 2014: Sending information letters to parents

September 2015- January 2015: Planning and performing measurements

January 2015: analyze data

Onderzoeksproduct en/of interventie

Questionnaires (general, ISAAC, PAQ C)

Ergometrie

Spirometrie

Lung Clearance Index

Contactpersonen

Publiek

Pediatric Pulmonologist

UMCG/Beatrix Children's Hospital CA 43

Department of Pediatric Pulmonology and Pediatric Allergologie

PO BOX 30.001

E.J.L.E. Vrijlandt
Groningen 9700 RB
The Netherlands
+31 50 3612475

Wetenschappelijk

Pediatric Pulmonologist

UMCG/Beatrix Children's Hospital CA 43

Department of Pediatric Pulmonology and Pediatric Allergologie

PO BOX 30.001

E.J.L.E. Vrijlandt
Groningen 9700 RB
The Netherlands
+31 50 3612475

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Research group

- Born between 32 and 36 +6 weeks of gestation
- From one of the three northern provinces (Drenthe, Groningen and Friesland)

Control group

- Born after 37 weeks gestation
- From one of the three northern provinces (Drenthe, Groningen and Friesland)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Research group

- Duration of pregnancy precisely determined by ultrasound
- Physical inability to carry out fietsergometrietest
- Birth Defects
- Illness or fever at the time of measurement

Control group:

- Duration of pregnancy is not exactly determined by ultrasound
- Physical inability to carry out fietsergometrietest
- Birth Defects
- Use of bronchodilators
- Illness or fever at the time of measurement

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4444
NTR-old	NTR4567

Register

Ander register

ID

: not yet available

Resultaten