Lung function and exercise capacity in late preterms

Published: 24-08-2010
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Research of lung function and exercise capacity in late preterms (32-36 weeks gestation) in comparison with term born controls of 8 years

Ethical review	Not approved
Status	Will not start
Health condition type	Congenital respiratory tract disorders
Study type	Interventional

Summary

ID

NL-OMON35437

Source
ToetsingOnline

Brief title
Lung function in late preterms

Condition

- Congenital respiratory tract disorders

Synonym
preterm infants

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Astmabestrijding

Intervention

Keyword: exercise capacity, follow up, late preterms, lung function

Outcome measures

Primary outcome

Spirometry: FEV1,

Total lung capacity: RV/%TLC,

diffusion capacity: Dlco,

nitrogen monoxide: FeNO

provocation test: PD20 metacholine

exercise test: VO2 max.

Secondary outcome

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

Total lung capacity: TLC, TGV, RV , Raw, sGaw

diffusion capacity: DLco va, Kco

resistance measure: Rrs6

exercise test: Heart rate max, heart rate reserve, breathing frequency, maximal load, VO2 rest, breathing frequency, VT , VTmax, VEmax, ventilatory reserve, VO2 at AT, VO2max, AT, AT/ VO2, ΔVO2/ ΔWR, respiratory exchange ration, borg score

-for comparison of the RSV admitted children with the non-RSV-admitted children the same studyparameters will be used.

-Sensibility, specifity and ROC-curves will be calculated to determine the most discriminative test

Study description

Background summary

Preterm children (<32 weeks gestation) have more respiratory complaints and more abnormalities in lung function tests compared to term born children. Little is known about lung function and exercise capacity in children born in 32-36 weeks gestation, the so called "late" preterms.
The last stage of lung development (alveolarisation) begins around 32-36 weeks gestation. When a child is born before or during this stage, problems could arise in: alveolarisation, vascularisation and/or damage by treatment. Children hospitalized due to Respiratory Syncitial Virus suffer chronic respiratory morbidity. The RS-hospitalized preterm children are at very high risk for such an adverse outcome. Therefor they are invited as a seperate group.

Study objective

Research of lung function and exercise capacity in late preterms (32-36 weeks gestation) in comparison with term born controls of 8 years

Study design

cross-sectional research design
The lung function testing contains: spirometry, diffusion capacity, total lung capacity, a resistance measure with a forced oscillation technique, nitrogen monoxide in the expired air, an exercise test and a provocation test with metacholine.

Intervention

an exercise test and a provocation test with metacholine

Study burden and risks

The burden associated with participation is due to the lung function tests, particularly the bronchial challenge test. Each lung function test takes about 20-30 minutes and asks active cooperation of the participant. However metacholine could provoke bronchoconstriction, or narrowing of the airways. People with pre-existing airway hyperreactivity, such as asthmatics, will react to lower doses of metacholine compared to controls who will not react. The degree of narrowing can then be quantified by spirometry. A bronchodilator (salbutamol) is administered to counteract the effects of the bronchoconstrictor. In the exercise test participants will be asked to continue as long as possible. Most children see this as a challenge. The risk of these tests is very small. Each year these tests are performed by many children without serious complications. According to European guidelines lung function tests like spirometry and NO measures are seen as riskless. Provocation tests like an exercise test and metacholine challenge are seen as

tests with a limited risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Late Preterms: 40 children of the 'Pinkeltje' cohort with pregnancy duration 32-36 weeks.
Term born children: 40 children of the 'Pinkeltje' cohort with pregnancy duration 38-41 weeks.
All living in Friesland, Groningen or Drenthe.
All children from the 'Pinkeltje' cohort who are hospitalised because of RSV (n=39)

Exclusion criteria

Children with major congenital abnormalities
Children who are not able to perform a lung function test and/or an exercise test

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	119
Type:	Anticipated

Ethics review

Not approved

Date:	24-08-2010
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL27026.000.10