BaLoN: Infant lung function reference values

Published: 30-05-2012
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In this study we will provide reference values using the single occlusion technique in healthy infants aged 2 months - 1 year.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational non invasive

Summary

ID

NL-OMON38299

Source
ToetsingOnline

Brief title
BaLoN

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Respiratory disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Infants, Lung function

Outcome measures

Primary outcome

The main study parameter is the single occlusion technique.

Secondary outcome

Besides lung function, we will measure body weight and body height.

Study description

Background summary

Wheezing illnesses are the most common cause of morbidity and mortality in infancy and childhood and have a large impact on health care. (Katier et al. zie intro)
It is important to recognise the child that is at risk for severe acute or chronic respiratory disease as early as possible during infancy or childhood. Adequate treatment and prevention might prevent long term morbidity. Katier et al. showed that feasibility and variability of lung function testing using the SOT is acceptable for use in large populations of healthy neonates and infants in routine care. In another study Katier et al. provided reference values for healthy neonates. Participants of this study were recruited as part of the Whistler-project and were all < 2 months. No reference values exist in children > 2 months.

Study objective

In this study we will provide reference values using the single occlusion technique in healthy infants aged 2 months - 1 year.

Study design

This study has a cross-sectional design. The participants will be derived from day nurseries which are willing to participate.

Study burden and risks

There are no risks associated with participation in this study. There is no benefit for the children in participating to this study and participation is completely voluntary. We will conduct our study according to the code of

conduct in case of resistance of the Dutch Assocation of Paediatrics (NVK).

Contacts

Public
Universitair Medisch Centrum Utrecht

Lundlaan 6
3508 AB Utrecht
NL
Scientific
Universitair Medisch Centrum Utrecht

Lundlaan 6
3508 AB Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Healthy children at a day nursery

Exclusion criteria

- Children with a history of neonatal respiratory disease.
- Children with a disease which could influence pulmonary function, like thoracic malformations or abnormal growth.

- Children with gestational age <36 weeks

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-02-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	30-05-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL36892.041.11