

# Validation of the Paediatric Electronic quality of Life Instrument for Childhood Asthma in the Netherlands.

Published: 17-10-2008

Last updated: 11-05-2024

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Bronchial disorders (excl neoplasms)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON32237

### Source

ToetsingOnline

### Brief title

Pelican project

### Condition

- Bronchial disorders (excl neoplasms)

### Synonym

asthma, bronchial asthma

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Nederlands Astmafonds

## Intervention

**Keyword:** Asthma, pediatric, Quality of Life, Validation

## Outcome measures

### Primary outcome

The Pelican instrument should have the following (clinimetric) characteristics: has a high internal consistency and is able to detect relevant changes in HRQL within an individual child aged 6 to 12 years (evaluative capacity of the instrument). Moreover, the validity of the individualised part of the instrument should be good and the instrument is comprehensible, serviceableness and acceptable according to the children.

### Secondary outcome

The Pelican instrument should have the following (clinimetric) characteristics: is able to discriminate between relevant groups; is valid based on cross-sectional construct validity; is reliable and valid for children with asthma aged 4 or 5. Next the influence of a reminder on the reliability of the children\*s answers will be evaluated.

## Study description

### Background summary

Health-related quality of life (HRQL) is the complex of all aspects of an individual\*s subjective experience that relate both directly and indirectly to health, disease, disability and impairment. Assessment of HRQL for children with asthma in daily care may facilitate shared decision-making and contribute to patient-centered care, which could result in improvement adherence to treatment, asthma control, HRQL and satisfaction with received care. Currently there is no appropriate pediatric asthma-specific HRQL instrument for use in daily care that is feasible for daily care. In a recent study we have developed

an electronic HRQL instrument to fill this gap. This so-called \*Pelican\* instrument is designed as a webbased computer game.

### **Study objective**

The objective of this project is to establish the validity, reliability and responsiveness of a self-administered electronic asthma-specific quality of life instrument for childhood asthma. Since the Pelican instrument is developed to evaluate HRQL in daily care it is especially important that the Pelican instrument is able to detect relevant changes in HRQL within a child.

### **Study design**

Clinimetric study (no intervention) with a follow up of 2-months for asthmatic children (3 visits) and one visit for the reference population.

### **Study burden and risks**

Minors are asked to participate in this non-therapeutic trial. Since the Pelican-instrument is an instrument developed to assess the HRQL of asthmatic children, it is not possible to use other subjects (like adults). The results of this trial could result in benefits for children with asthma in general. The risk of participation is negligible. The children (and parents) are asked to fill out questionnaires. Moreover, the fraction of exhaled nitric oxide and lung function is assessed. For the lung function assessment salbutamol is used. In general, children with asthma use salbutamol or similar medication to relieve symptoms. Though very infrequent, the use of salbutamol can result in some side-effects.

## **Contacts**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

For the asthmatic children

- \* age 4 to 12 years
- \* signed informed consent by parent (or caretaker)
- \* child agrees to participate in the study
- \* at least two prescriptions for inhaled asthma medication during the previous year
- \* use of inhaled asthma medication for at least six weeks during the previous year
- \* physician-diagnosed asthma (a symptom diagnose asthma by a physician in case the child is 4 or 5 years old ) ;For the healthy individuals (reference population)
- \* age 6 to 12 years
- \* signed informed consent by parents (or caretakers)
- \* child agrees to participate in the study

### Exclusion criteria

For all children

- \* comorbid condition that significantly influences HRQL
- \* child does not master the Dutch language sufficiently
- \* not being able to attend a regular school class

## Study design

### Design

**Study type:** Observational non invasive

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

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	275
Type:	Anticipated

## Ethics review

Approved WMO	
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL23004.091.08