Effectiveness of the Paediatric Electronic quality of Life Instrument for Childhood Asthma in the Netherlands (Pelican) in medical care.

Published: 21-01-2010
Last updated: 04-05-2024

The objective of this study is to evaluate effects of the use of the Pelican instrument in routine medical care for asthmatic children in primary and secondary care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON32734

Source
ToetsingOnline

Brief title
PELICAN II project

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Nederlands Astmafonds;Stichting Nuts Ohra

Intervention

Keyword: Asthma, pediatrics, Quality of Life

Outcome measures

Primary outcome

Asthma-specific health related quality of life of the children as measured with the Pediatric Asthma Quality of Life Instrument

Secondary outcome

Secondary outcomes are measures of asthma control, asthma medication use, lung function, NO, asthma symptoms, costs (i.e. program costs, direct medical and indirect costs), and satisfaction with delivered health care in children as well as in their parents and physician. Next, facilitators and barriers of implementation of the Pelican instrument in primary and secondary care are assessed. To address this, the process of the implementation of the instrument in both randomised trials will be evaluated. Also the caregivers (i.e., parents) health related quality of life is a secondary outcome.

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 improved 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 study is to evaluate effects of the use of the Pelican instrument in routine medical care for asthmatic children in primary and secondary care.

Study design

A 9-month clustered-randomised clinical trial is carried out in general practice (n=170 children), and a 9-month patient-randomised trial in paediatric outpatient clinics (n=100 children). Both trials consist of an intervention group in which physicians use the results of the Pelican instrument in their provision of asthma care and (b) usual care. All children fill out the Pelican instrument at 0, 3 and 6 mo, but feed-forward of the outcome is only provided to intervention group physicians.

Intervention

The intervention in the two studies is the integration of the output of the Pelican instrument in daily care to guide disease management for children with asthma.

Study burden and risks

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. If the child has a negative experience with a lung function test, the test is omitted.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

* age 6 to 12 years
* physician-diagnosed asthma
* child is treated for their asthma by the recruiting physician
* use of inhaled asthma medication for at least six weeks during the previous year

Exclusion criteria

* 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:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2010
Enrollment:	270
Type:	Actual

Ethics review

Approved WMO Date:	21-01-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-12-2011
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-03-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-07-2012
Application type:	Amendment
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	NL29895.091.09