Development of an instrument to measure quality of life in children with bronchopulmonary dysplasia

Published: 18-10-2011
Last updated: 28-04-2024

The development of a disease specific questionnaire to measure the quality of life in children with BPD at age 4-8, that can be answered by the parents.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON35138

Source
ToetsingOnline

Brief title
Development of a QoL questionnaire for children with BPD

Condition

- Neonatal and perinatal conditions
- Neonatal respiratory disorders

Synonym
chronic lung disease after preterm birth, hyalin membrane disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bronchopulmonary dysplasia, children, quality of life, questionnaire

Outcome measures

Primary outcome

The developed disease specific questionnaire for BPD.

Secondary outcome

Outcome value of lung function tests (spirometry), ecg characteristics, length

and weight, bloodpressure, IQ-test and of the questionnaires for behaviour and

development.

Outcome of the questionnaire about medical information and familysituation and

-information that is relevant to the outcome of the study.

Study description

Background summary

The new form of Bronchopulmonary Dysplasia (BPD) describes the effects of an incomplete development of the lungs in (extreme) premature born children with an underdeveloped microanatomical structure and a decrease in alveolairy surface. There is a growing incidence because of the better survival of extreme premature children. In the past years it was found repeatetly that children with BPD are different from premature born children without BPD and normal children, also at older age. There is no information available about the influence of BPD on the quality of life. Measuring quality of life can be done with a disease specific questionnaire. These are not available for BPD. But with a good methodology it could be developed. A questionnaire for BPD can be relevant to determine the impact of BPD between different patients, but also to measure differences within a patient over time, for example in a treatment course. This will be an important step forward on the way to developing an evidence based treatment for BPD at older age.

Study objective

The development of a disease specific questionnaire to measure the quality of

life in children with BPD at age 4-8, that can be answered by the parents.

Study design

This is a cohortstudy at the deparment of children pulmonology of the Universitary Medical Centrum Groningen (UMCG). The development of a disease specific questionnaire starts with the collection of items that are relevant. This will be done by literature research, interviewing specialists on this subject and interviewing patients and/or their parents. Then the list of items will be reduced by asking a group of patients about the relevance of the items idependently. After this, the list of questions needs to be validated. Because there is no gold standard available, we need to use construct validation. This means that an independent outcome, that is related to what you want to measure, will be used to validate the strength of the questionnaire. There must be a correlation between existing measurements and the questions developed. Only the validated questions will be used in the final questionnaire.
Because the study concerns a population of children, the tests are chosen to be of very common use, easy to perform and of no risk. Another reason to choose commonly used tests is because the results will be easier to interpret. To validate the questions about pulmonary problems a lung function test will be performed, for feeding problems lenght and weight will be measured. To validate problems concerning (pulmonary) hypertension, ecg and blood pressure will be taken. To measure behaviour and development, some (already validated) questionnaires will be used.

Study burden and risks

Filling in the questionnaires will be of no risk for the child. The tests that are selected are known to be very safe and easy to perform. Also there is a lot of experience with these kind of tests. The risk of unwanted side-effects is therefore very low. According to the European guidelines a lung function test like spirometry and making of an ecg is considered to have no risk. The tests are picked to be of very low burden for the patient and will be performed like that.
This study makes use of a population of children under 18 years old because a disease specific questionnaire for these children is only usefull when it is specifically designed in the same group. This is because the parameters for quality of life at this age are not comparable to that of older children or adults.
The important reason to select this group of children for to make a disease specific questionnaire is because healthrelated problems that effect the development can have long-term consequences at this age since it knows a big development.

Contacts

Public
Academisch Medisch Centrum

Hanzeplein 1
9713 GZ Groningen
NL
Scientific
Academisch Medisch Centrum

Hanzeplein 1
9713 GZ Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children that were discharged from the neonatal intensive care unit of the UMCT between 2003 and 2007, that met the current criteria for BPD.

Exclusion criteria

In case of death of the child or missing of current contact information.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2011
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO

Date:	18-10-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL37849.042.11

Study results

Date completed:	01-12-2012
Actual enrolment:	91