Exercise induced bronchoconstriction after hospitalisation for lower respiratory tract infection in infancy

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Main objective of this study is to investigate the prevalence of EIB in young children with a history of hospitalisation for VLRTI, using an exercise provocation challenge adjusted to the specific age-related course of EIB.

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

Summary

ID

NL-OMON37579

Source
ToetsingOnline

Brief title
EIB after VLRTI

Condition

- Bronchial disorders (excl neoplasms)

Synonym
bronchiolitis, exercise induced asthma, exercise induced bronchoconstriction, lower respiratory tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Pediatrisch Onderzoek Enschede

Intervention

Keyword: asthma, bronchiolitis, exercise induced bronchoconstriction, lower respiratory tract infection

Outcome measures

Primary outcome

Primary outcome of this study is to investigate the prevalence of EIB in young children with a history of hospitalisation for VLRTI. Primary parameter is the percent change in pulmonary function (FEV0.5) during and post-exercise in young children, hospitalised in infancy with VLRTI.

Secondary outcome

Secondary objectives are:

-The percent change in other pulmonary function parameters (FEV1, FEF50) during and post-exercise in young children, hospitalised in infancy with VLRTI.

-To compare the prevalence of EIB in young children with a history of VLRTI caused by different pathogens (RSV versus RV)

-The analysis of anthropometric measures, clinical features, medication use and (microbiologic) history of young children with a history of hospitalisation for VLRTI

-To investigate whether the prevalence of asthma in young children with a history of hospitalisation for VLRTI significantly differs from the prevalence of asthma in the general population (based on literature data; in the Netherlands between 5-10% in children aged 4-12).

Study description

Background summary

Hospitalisation for bronchiolitis in infancy is a well-known risk factor for later asthma. Bronchiolitis is a viral lower respiratory tract infection (VLRTI), affecting infants <2 years of age. Respiratory syncytial virus (RSV) and rhinovirus (RV) are the predominant viruses, associated with severe VLRTI in infancy. Few prospective studies have examined the development of asthma in children with a history of VLRTI by using an exercise provocation challenge, which is an indirect provocation test highly specific for asthma. These exercise challenge tests were not standardized and pulmonary function measurements were performed only 5, 10 and 15 minutes after exercise, which probably underestimates the prevalence of exercise induced bronchoconstriction (EIB) in these children.

Study objective

Main objective of this study is to investigate the prevalence of EIB in young children with a history of hospitalisation for VLRTI, using an exercise provocation challenge adjusted to the specific age-related course of EIB.

Study design

This study is a prospective cohort study.
Patients will undergo an extensive evaluation of their asthma, including a history, physical examination and an exercise provocation challenge. This exercise provocation challenge exists of jumping on a jumping castle for at least 4 minutes (target is a 6 minute lasting exercise at 80% of the predicted maximum heart rate). Before, during and after exercise, patients perform pulmonary function measurements (flow volume curves). Exercise induced bronchoconstriction is defined as a >13% fall in FEV0.5 after exercise. If bronchoconstriction persists 15 minutes post-exercise (i.e. FEV0.5 less than 95% from baseline value) or at childrens request, 100 µg salbutamol will be administered and a flow volume loop will be repeated 5 minutes after salbutamol to establish recovery.
The exercise provocation challenge takes place in the skating rink, because the air condition (cold and dry) is standardized and reflects the mean air condition in Holland (*real life test*). Moreover, an exercise challenge in dry air is a more sensitive test to diagnose exercise induced bronchoconstriction. Children with a negative exercise provocation challenge will be invited to a second challenge on another day, to prevent false negative results.

Intervention

The intervention is an exercise provocation challenge. This exercise challenge exists of jumping on a jumping castle for at least 4 minutes (target is a 6 minute lasting exercise at 80% of the predicted maximum heart rate). Before, during and after exercise, patients perform pulmonary function measurements (flow volume curves).
The exercise provocation challenge takes place in the skating rink, because the air condition (cold and dry) is standardized and reflects the mean air condition in Holland (*real life test*). Moreover, an exercise challenge in dry air is a more sensitive test to diagnose exercise induced bronchoconstriction. Children are involved in all kinds of exercise all day long and for children, exercise is a way of recreation. Our exercise challenge (jumping on a jumping castle) was especially designed for young children and is a child-friendly and safe way of exercise. Experience from previous research (a pilot study and study NL38021.044.11) with the same exercise challenge has learned us that children enjoy performing the test. For these reasons we believe that our intervention is not harmful to the children.

Study burden and risks

The risks of participation are considered minimal.
Patients have to undergo an exercise provocation challenge with the chance of getting dyspnoeic. Especially in children, exercise limitation is a heavy burden on the quality of life, however the exercise challenges alone pose a minimal risk. The possible dyspnoea is comparable to that experienced when exercising in real life and children generally consider this as a minimal burden. When indicated (i.e. if bronchoconstriction persists 15 minutes after exercsie or at patients request) salbutamol will be administered. If children become dyspnoeic during exercise, exercise will be terminated. With the development of the design of our exercise provocation challenge, the age of the children is taken into consideration. We tried to minimize the burden of exercise by using a jumping castle. Experience from previous research (a pilot study and study NL38021.044.11) with the same exercise challenge has learned us that children enjoy performing the test. For these reasons we believe that our intervention is not harmful to the children.The benefit is that patients (and parents) get an evaluation of the extent of their asthma. This study must be performed in this young patient group, because diagnosing asthma at this age enables early therapeutic intervention, thereby preventing long term remodelling of the asthmatic airways. Moreover, we would like to compare our results with the scarce existing data,in this age group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- History of hospitalisation for viral lower respiratory tract infection (VLRTI) <2 years of age (subjects will be recruited from VLRTI cohort)
- Age 5 through 7 years
- Ability to perform reproducible lung function tests, i.e. coefficient of the predicted value variation in 3 of 5 consecutive measurements < 5%
- Clinically stable period at least 4 weeks before the study period (no hospital admission or use of systemic corticosteroids)

Exclusion criteria

-Use of systemic corticosteroids in the last 4 weeks prior to the study
-Use of long acting bronchodilators 24 hours before testing
-Use of short acting bronchodilators 8 hours before testing
-Use of leukotriene antagonists 24 hours before testing
-Comorbidity (other pulmonary or cardiac disorder, mental retardation/motor dysfunction)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-03-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	01-03-2012
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

ID: 24718
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL38731.000.12
Other	NTR nr volgt
OMON	NL-OMON24718