Fractional concentration of nitric oxide in exhaled breath in children aged 7-10: survey in a primary health care setting

Published: 02-06-2009
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The aim of this study is to assess the relation between elevated FENO and undiagnosed asthma.

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

Summary

ID

NL-OMON33345

Source
ToetsingOnline

Brief title
FENO in children aged 7-10: survey in a primary health care setting

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma, asthma symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: De huisartspraktijk in samenwerking met de afdeling Huisartsgeneeskunde van het Erasmus MC

Intervention

Keyword: asthma, children, cross-sectional survey, FENO

Outcome measures

Primary outcome

Main study parameters are the ISAAC questionnaire for asthma, rhinitis and eczema, spirometry (FEV1 and FVC), airway reversibility testing with salbutamol and FENO. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of FENO and airway reversibility in undiagnosed asthma in children aged 7-10 years will be analysed.

Secondary outcome

Not applicable

Study description

Background summary

The results of the clinical and epidemiological studies up until now urge the need for further studies on the usefulness of FENO (fractional exhaled nitric oxide) in the clinical management of undiagnosed asthma. In subjects aged 7-10 years there is a window of opportunity to diagnose childhood asthma through the combination of clinical data and spirometric lung function including FENO as a measure of airway inflammation.

Study objective

The aim of this study is to assess the relation between elevated FENO and undiagnosed asthma.

Study design

The design of this study is a cross-sectional study in all primary care centres in Brielle, the Netherlands.

Study burden and risks

The burden of participation is to complete the ISAAC questionnaire and to having assessed length, height, FEV1, FVC, reversibility of airway obstruction with salbutamol and FENO in one visit. Short during side effects of salbutamol can be an additional flavour in the mouth after inhalation or more common symptoms as nausea or headache.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

alle children aged 7-10 years

Exclusion criteria

Children with a doctor*s diagnosis of asthma and asthma medication in the past twelve months.
Children with a contra-indication for salbutamol.

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):	03-06-2009
Enrollment:	450
Type:	Actual

Ethics review

Approved WMO

Date:	02-06-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL26360.078.08