Tidal breathing FENO measurements: a new algorithm

Published: 07-01-2011
Last updated: 30-04-2024

Primary objective: to assess the correlation and agreement between the new TB technique and the conventional SB online technique with constant expiratory flow.Secondary objective: to investigate the reproducibility of this new technique.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational non invasive

Summary

ID

NL-OMON34300

Source
ToetsingOnline

Brief title
Tidal breathing FENO: a new algorithm

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
n.v.t.

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Philips

Intervention

Keyword: children, FENO, tidal breathing

Outcome measures

Primary outcome

Correlation and agreement of FENO as measured by the two different techniques.

Secondary outcome

Reproducibility of FENO measured by the TB technique.

Study description

Background summary

Fractional exhaled nitric oxide (FENO)
A large number of studies have shown that the fractional concentration of nitric oxide in exhaled air (FENO) is a non-invasive marker of eosinophilic airway inflammation. Elevated FENO in atopic asthma is attributed to the induction of NO-synthase (iNOS) by proinflammatory cytokines and mediators leading to the increased production of NO by the airway epithelium.

Methodology
Several factors are known to influence FENO measurements. Most important factors are expiratory flow, ambient nitric oxide and nasal nitric oxide. FENO is highly flow-dependent, with higher flows resulting in lower FENO.
In adults and older children international guidelines recommend to measure FENO during a single slow exhalation from total lung capacity at a constant flow of 50 ml/s. Exhalation against a resistance ensures soft palate closure and avoids nasal NO contamination. This method is unsuitable in uncooperative patients, and the proportion of reliable measurements drops dramatically below the age of 5 to 6 years.
In preschool children tidal breathing (TB) methods with a mask or mouthpiece have been used to measure FENO. These methods have been shown feasible, reproducible and discrimination between groups with different respiratory diseases has been possible with these techniques. However, with the TB method it is especially hard to control for expiratory flow, and results are insufficiently accurate for use in individual patients.

Clinical applications in pediatrics
FENO measurements are able to discriminate between children with and without

untreated asthma. In preschool children FENO might be a useful diagnostic tool which can help to differentiate between children with transient wheeze (for example due to respiratory infections) and children who wheeze due to asthma, with underlying chronic eosinophilic airway inflammation.
Furthermore, several authors found lower FENO levels in patients with asthma after treatment with inhaled or oral steroids. Pijnenburg et al. showed that FENO may be an objective predictor of asthma relapse after discontinuation of steroids in symptom free asthmatic children. Titration of inhaled steroids on FENO and symptoms and/or lung function showed modest effects on bronchial hyper responsiveness, lung function, and prednisone use. Therefore FENO measurements seem to be useful not only as a diagnostic tool but also in the monitoring of asthmatic children.

Study objective

Primary objective: to assess the correlation and agreement between the new TB technique and the conventional SB online technique with constant expiratory flow.

Secondary objective: to investigate the reproducibility of this new technique.

Study design

Cross sectional design.

The data will be collected at the outpatient clinic of KinderHaven, a specialized asthma clinic located at the Haven Hospital. At a routine visit FENO will be measured with the new TB technique and with the conventional SB online technique with constant expiratory flow of 50 ml/s. Furthermore, the reproducibility of the new TB technique will be tested by performing the tidal breathing FENO measurement twice. The study will be performed within 1 routine visit for each study subject. We expect to need 3 months for including patients and collecting all data.

Study burden and risks

When children and their parents agree to participate to this study the research data will be collected during a routine visit and this will only take a couple of minutes extra time. This new developed technique to measure FENO during tidal breathing is particularly of value for children. The children who participate in this study will not personally benefit from the results. If this new technique proves to be reliable and comparative to the conventional technique it will be possible to measure FENO also in younger children. In preschool children, FENO measurements can possibly contribute to the early diagnosis of asthma but also to the improvement of treatment and prevention of

exacerbations.

Contacts

Public
Philips

High Tech Campus 34 (WB 1.031)
5656 AE Eindhoven
NL
Scientific
Philips

High Tech Campus 34 (WB 1.031)
5656 AE Eindhoven
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

All children aged 6-18 years that visit the outpatient clinic and need to perform a conventional single breath (SB) FENO measurement as part of the standard diagnostic care will be invited to participate in the study.

Exclusion criteria

Mental retardation, and otherwise children who are not able to perform a conventional FENO measurement.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-02-2011
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	EcoMedics CLD88sp + DENOX 88 module
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-01-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	10-03-2011
Application type:	Amendment
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	NL32208.078.10