Exhaled Nitric Oxide in healthy children 1 - 4 years old

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The aim of this study is to establish reference values of exhaled nitric oxide (eNO) using the tidal breathing offline method in healthy children aged 12 - 48 months (1 - 4 years old).

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-OMON32593

Source
ToetsingOnline

Brief title
Exhaled Nitric Oxide in healthy children 1 - 4 years old

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
asthma, astma

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: Stichting ter bevordering van de Kindergeneeskunde Nijmegen

Intervention

Keyword: Child, Nitric Oxide

Outcome measures

Primary outcome

exhaled NO (in parts per billion)

The mean eNO concentration, the standard deviation and the 95% reference

interval (RI) for the eNO will be calculated. The 95% reference interval will

be considered as reference values.

Secondary outcome

Not applicable

Study description

Background summary

Nitric oxide in exhaled air (FeNO, fractional exhaled nitric oxide) is a marker of airway inflammation. Airway inflammation is a characteristic feature of asthma, so measurement of FeNO is a useful test for diagnosing and monitoring asthma. Because measurement of FeNO is a non-invasive procedure, it is extremely useful for children.

For adults and children older than 6 years of age, recommendations for standardized procedures for FeNO measurement have been outlined. However, for these standardized procedures, considerable collaboration on the part of the patient is necessary, which is almost impossible in children younger than 5 years of age. For children younger than 5 years of age, several methods for eNO-measurement have been developed, which only require passive collaboration of the child. One of these methods is the tidal breathing offline eNO-measurement: no sedation is needed and the method is easily applicable in toddlers. Although this method was described several times, no reference values are available for children aged 1 - 4 years old. Before tidal breating offline eNO-measurement can be used in daily practice, reliable reference values have to be established for this group of children.

Study objective

The aim of this study is to establish reference values of exhaled nitric oxide (eNO) using the tidal breathing offline method in healthy children aged 12 - 48 months (1 - 4 years old).

Study design

We will measure eNO once in 50 healthy children aged 12 - 48 months (1 - 4 years old), using the tidal breathing offline method. When the child is in its mother's or the investigator's lap, the exhaled air of the child is collected in 2 balloons using a face mask. The NO-concentration in the exhaled air will be analysed the same day, using the NO-analysator (Niox flex). NO-measurement is an ozon/NO2-based chemiluminescence reaction. The NO in the balloon remains stable during 9 hours.

Study burden and risks

There is no significant burden for the participants: when the child is in its mother's or the investigator's lap, the exhaled air of the child is collected in 2 balloons using a face mask. When the child offers resistance (for example crying or pushing the face mask away), the measurement will be stopped. The study involves no risks for the participants.

Contacts

Public
Canisius Wilhelmina Ziekenhuis

Weg door Jonkerbos 100
6532 SZ Nijmegen
Nederland
Scientific
Canisius Wilhelmina Ziekenhuis

Weg door Jonkerbos 100
6532 SZ Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Healthy children aged 12 - 48 months (1 - 4 years old)

Exclusion criteria

- Medical history of: asthma, viral wheeze, eczema, allergic rhinitis or other allergies/pulmonary diseases
- An active upper or lower respiratory tract infection during the eNO-measurement
- Medication: β2-sympathicomimetics, inhalation corticosteroids, leukotriene receptor antagonists or antihistamines

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):	24-01-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	16-02-2010
Application type:	First submission
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	NL30243.091.09