Impact analysis of the Fractional exhaled Nitric Oxide (FeNO) test as add-on test in the diagnostic work-up of asthma

Published: 28-03-2023
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This study calculates the cost reduction of add-on FeNO testing compared to standard diagnostic, to finally support FeNO testing in guidelines.

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

Summary

ID

NL-OMON53629

Source
ToetsingOnline

Brief title
INFERNO

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland
Source(s) of monetary or material Support: BOF subsidie Franciscus Gasthuis & Vlietland

Intervention

Keyword: Asthma, Asthma guideline, Bronchial Challenge, Diagnostics, Fractional exhaled Nitric Oxide

Outcome measures

Primary outcome

Main study endpoint:

• (Theoretical) reduction of BPTs

Secondary outcome

Secondary endpoints:

• Direct healthcare costs of diagnosis (avoidable BPTs, extra costs of FeNOs,

extra diagnose costs in FeNO >= 50 ppb and negative BPT)

• The diagnostic burden of FeNO testing and BPT testing (VAS -score and AQLQ)

• Asthma control (ACQ)

Secondary parameters:

- Patient characteristics

- Asthma profile (eosinophils, sIgE to inhalation allergens)

- Lung function (FEV1 and Forced Vital Capacity (FVC) and FVC/ FEV1)

- Outcome BPT (positive/negative)

- FeNO test outcome (ppb)

Study description

Background summary

The Global Initiative of Asthma Guideline (GINA) recommends a flowchart to diagnose asthma with spirometry (with reversibility) and as a second step a bronchial provocation test (BPT) with histamine or methacholine (1). However, the BPT is considered as burdensome, not without risk, and expensive (2). In addition, this time-consuming test strongly encumbers the lung function capacity.
This is a prospective implementation study investigating a *new diagnostics work-up* with the Fractional exhaled Nitric Oxide (FeNO) test as an intermediate step between the spirometry with reversibility and the BPT, with the aim to determine the impact of the FeNO-based strategy, in terms of (theoretical) number of avoided BPTs, cost reduction and reduced burden to the patient. So, this study is intended to demonstrate the added value of the FeNO test as an *add-on* test incorporated in the diagnostic flow-chart (not a stand-alone diagnostic tool) for asthma diagnostics and with the ultimate goal of implementing the FeNO test in the diagnostic algorithm for asthma in the guidelines. This is also the first study that investigates the cost reduction of incorporating the FeNO test in the diagnostic flowchart.

Study objective

This study calculates the cost reduction of add-on FeNO testing compared to standard diagnostic, to finally support FeNO testing in guidelines.

Study design

Prospective implementation study

Intervention

Standard care
• Consult pulmonary physician
• Blood sampling
• Spirometry
• Visual Analogue Scale (VAS) and Asthma Quality of Life Questionnaire (AQLQ)
• Asthma Control Questionnaire (ACQ)

Visit 1
• The patient will be asked for informed consent and to complete a self-made questionnaire to obtain general information about the patient*s characteristics before the diagnostic procedure
• FeNO measurement
• BPT
• VAS and AQLQ

Standard care

• ACQ after 3 months of treatment

Study burden and risks

This study has a low burden for the participating patients because the new diagnostic work-up in this study does not differ much from the standard diagnostic work-up. Only the FeNO test (which takes 5 minutes), a very simple and low-burden lung function test is extra. The blood sampling is the same as in routine diagnostics for asthma. The questionnaires after each diagnostic test and after 3 months will take 5 minutes extra per questionnaire.

Contacts

Public
Franciscus Gasthuis & Vlietland

Kleiweg 500
Rotterdam 3045PM
NL
Scientific
Franciscus Gasthuis & Vlietland

Kleiweg 500
Rotterdam 3045PM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patients >= 18 years, referred by the general practitioner to the outpatient clinic pulmonology with the suspicion of asthma
• Patients without reversibility at the spirometry (delta FEV1 >= 200 ml and >=12% improvement)
• Patients understand the Dutch or English language for giving informed consent and to complete the questionnaires
• They can discontinue their medication (discontinuation time depends on the kind of medication, paragraph 3.2)

Exclusion criteria

Patients will be excluded if:
• They have a fixed obstruction or with already the diagnose with asthma based on prior tests
• They are pregnant

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2023
Enrollment:	171
Type:	Actual

Ethics review

Approved WMO

Date:	28-03-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-04-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL81129.100.23