Diagnosis of asthmatic patients using impulse oscillometry; a simple alternative to spirometry.

Published: 17-07-2017
Last updated: 13-04-2024

Determine the diagnostic accuracy of the AX area of the impulse oscillometry for asthma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON45914

Source
ToetsingOnline

Brief title
Diagnosing asthma with impulse oscillometry/DAWIO

Condition

- Respiratory disorders NEC

Synonym
asthma, asthma bronchiale

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Haaglanden Medisch Centrum

Intervention

Keyword: asthma, diagnosis, impulse, oscillometry

Outcome measures

Primary outcome

The change of the AX area of the impulse oscillometry after taking Ventolin in comparison with the diagnosis of the pulmonary phycicians. The change of the AX area will be used to create an ROC-curve and the best cut off value will be determined. For this cut off value the sensitivity, specificity, positive prediction value, negative prediction value, positive likelihood ratio, negative likelihood ratio and diagnostic odds ratio will be determined, including their 95% confidence intervalls.

Secondary outcome

The change of the R5 and X5 of the impulse oscillometry after Ventolin in comparison with the diagnosis of the pulmonary phycicians. The change of the R5 and X5 area will be used to create an ROC-curve and the best cut off value will be determined. For this cut off value the sensitivity, specificity, positive prediction value, negative prediction value, positive likelihood ratio, negative likelihood ratio and diagnostic odds ratio will be determined, including their 95% confidence intervalls.

The change of the FEV1 of spirometry after Ventolin in comparison with the diagnosis of the pulmonary phycicians. The Mcnemar test will be used to see if there is a significant difference between the diagnostic accuracy of the FEV1 of spirometry in comparison with the AX area of the impulse oscillometry.

The correlation between the R5, R20 and AX with the FEV1 will be determined.

Study description

Background summary

The impulse oscillometry is a simple pulmonary function test wich isn't widely used in clinical practice. The measurement is not dependent on the effort of the patient and causes a minimal amount of stress. Current literature shows that the impulse oscillometry can be used in reversibility tests and inhalation provocation tests.

Study objective

Determine the diagnostic accuracy of the AX area of the impulse oscillometry for asthma.

Study design

The study is a diagnostic accuracy study (cross sectional) between the dianosis of the pulmonary phycicians and the impulse oscillometry.

Study burden and risks

The extra measurement costs very little time and is not taxing for patients, no additional risk is involved.

Contacts

Public
Haaglanden Medisch Centrum

Lijnbaan 32
den Haag 2512VA
NL
Scientific
Haaglanden Medisch Centrum

Lijnbaan 32
den Haag 2512VA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult patients (18 years and older) who are redirected to a secondary health care institute with the presumed diagnosis of asthma who have given informed consent to be included in the study.

Exclusion criteria

Minors below 18 years of age, incapacitated adults and subject who have not signed the informed consent form.

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):	02-10-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	17-07-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL61597.098.17