Reference value research for instantanious resistance and impulsoscillometrics

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Goal of the researchTo investigate whether the newly measured parameters are deviating, these should be compared to the values of the healty volunteers. The goal to achieve is the determination of the healthy values as follows:- Determine reference...

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-OMON32138

Source
ToetsingOnline

Brief title
Reference value research for Bodyplethysmography and impulsoscillometrics

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
airwayresistance, breathlessness

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: airwayresitance, Impulsoscillometrics, Lungfunction, Lungvolumes

Outcome measures

Primary outcome

To define reference values for the new measured parameters by

bodyplethysmographia and impulsoscillometrics.

Secondary outcome

Not relevant

Study description

Background summary

At our lungfunctiondepartment - and worldwide as well - airwayresistance has been measured as a part of the routine on patients by bodyplehysmographia and impulsoscillometrics (IOS for several years.
As a result of the recent upgrade of the computersoftware, extra information is available without any major change in the routine measuring procedures or the used hardware.
Because of the fact that we have to obtain new parameters, we need to measure reference values in a select group of healthy volunteers.
The absence of reference values according to persons by the age of 5 - 80 years of age measured by impulsoscillometrics, leaves the impossibility to recognise or evaluate the measured values according to these patients.

Study objective

Goal of the research

To investigate whether the newly measured parameters are deviating, these should be compared to the values of the healty volunteers. The goal to achieve is the determination of the healthy values as follows:
- Determine reference values for bodyplethysmographia and even more specific the instantaneous airwayresistance.
- Define the referencevalues and variationcoefficience of the impulsoscillometric measurement.
- Measure the effect of bronchodilatation on the measured values in both

bodyplethysmographia and impuls-
oscillometrics.

Study design

Reference value research

Study burden and risks

The volunteers experience no complications of the
bodypletysmographia/impulsosccilometric measurements.
Complications of Salbutamol are described in the medicinerepertory as follows:
- Ventolin inhaler, Volumatic and Babyhaler can cause tremor
- Temporary musclecramp is seldom reported
- These effects are being caused by the direct effect on the on the
skeletonmuscles
- These effect depend on the administrated dose and are general to all
beta-sympathicomimatics.
- Mouth and throat irritation can occur
- Within the range of an administrated dose periferal vasodilatation as well as
a smaal compensatory increase of the hartbeat frequently can occur.
- The chance on arythmia will increase on patients with hypocalcemia
- Some patients can show tachycardial symptoms
- defects of the heartbeatfrequency like atriumfibrillation, supreventricular
tachycardia, extrasystols are reported, mostly on patients who are sensitive
for defects od the haertbeatfrequency.
- Haedache, raise of sweat and idiosyncrasic reactions like angio oedemia,
uticavia, bronchospasm, hypertension and collaps are seldom reported.
- Hyperactivity and hallucinations on children are seldom reported.
- Like any other inhalationtherapy one should consider the possibility of
paradoxal bronchospasms (on first appearance of this, the current therapy needs
to be stopped at once and an alternative therapy has to be started)
-cardial complaints like angina pectoris, a recent heart attack (in less than
1/2 year).
- a modarate pumpfunction of the heart
- Claustrophobia
_ Allergic rhinitis
_ Ear-drumpperforation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age between 55-80 years
Non-smokers
No respirority diseases
Normal spirometry (FEV1>85%pred, FEV1/FVC>0,7).
Before the research longvolumes will be measured

Exclusion criteria

Hartdiseases like angina pectoris, a recent haert attack (in less than 1/2 year), a moderate pumpfunction of the heart
Claustrophobia
Allergic rhinitis
Ear-drumpperforation

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):	01-12-2008
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	10-11-2008
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	NL22463.078.08