

SMALL study: SMall Airways: a comparison of the Lung clearance index and other Lung function tests

Published: 03-03-2016

Last updated: 19-04-2024

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Ethical review

Approved WMO

Status

Recruitment stopped

Health condition type

Lower respiratory tract disorders (excl obstruction and infection)

Study type

Observational non invasive

Summary

ID

NL-OMON44068

Source

ToetsingOnline

Brief title

SMALL study

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym

healthy volunteers

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Stichting Astma Bestrijding

Intervention

Keyword: Lung Clearance Index, Multiple Breath Washout, Small airways

Outcome measures

Primary outcome

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Secondary outcome

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Study description

Background summary

Zie pagina 7 en 10-12 protocol

Study objective

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Study design

Pagina 8 en 14 protocol

Study burden and risks

pagina 24 protocol

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

Healthy adult volunteers age 18-65 years

Healthy pediatric volunteers age 6-18 years

Exclusion criteria

((History of)(passive) smoking, exclusion will take place when a subject has smoked in the last year, or has a smoking history of > 0.5 pack year (including e-cigarettes, water pipe and smoking of cannabis). According to the validated definition of the Dutch PYAMA study passive smoking is defined as exposure in the household or in another indoor setting more than 2 times a week.

(History of) chronic or severe lung or cardiac disease

Use of inhalation medication in the last year (steroids, salbutamol, ipratropiumbromide or other bronchodilators)

History of premature birth before 36 weeks of gestational age

Pregnant who are visually pregnant as judged by the investigator.

Fever, common cold or respiratory tract infection < 3 weeks before visit, as judged by the investigator

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): 01-12-2015

Enrollment: 40

Type: Actual

Ethics review

Approved WMO

Date: 03-03-2016

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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

CCMO

ID

NL54652.042.15