Measuring differences in breathing patterns between asthma patients and healthy subjects during physical exercise and the effect on the level of dyspnoea using respiratory inductance plethysmography

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To investigate the breathing patterns of asthma patients during exercise, compare this with the breathing pattern of healthy subjects and investigate whether the breathing pattern influences EID in patients with asthma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON50858

Source
ToetsingOnline

Brief title
The HexAs study

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma, Bronchial asthma

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: via onderzoeksbureau longgeneeskunde;Hexoskin vesten worden kostenloos beschikbaar gesteld door firma Hexoskin zonder verdere financiële betrokkenheid

Intervention

Keyword: Asthma, Breathing patterns, physical exercise, respiratory inductance plethysmography

Outcome measures

Primary outcome

The main study parameter is the breathing pattern. The breathing pattern is defined as the relative contribution of the breathing frequency (Bf), tidal volume (Vt), abdominal breathing and thoracic breathing to the respiratory minute volume and how these change during physical exercise. These parameters will be compared between all subjects and cluster analysis will be performed in order to define different breathing patterns.

Secondary outcome

The secondary goal of the study consist of the investigation whether certain breathing patterns can lead to EID. The level of dyspnoea will be objectified using BORG and visual analog scale (VAS) scores.

Study description

Background summary

Among the roughly 273 million people suffering from asthma worldwide, exercise induced dyspnoea (EID) is a common complaint. Additionally, 29% of patients

with asthma also suffer from dysfunctional breathing (DB) (an atypical breathing pattern leading to medical complaints) which is one of the main contributors to EID. However, EID is often attributed to exercise induced bronchoconstriction (EIB) and the possible effect of dysfunctional breathing on EID is unknown. Therefore, this study will investigate the breathing patterns of patients with asthma and compare these with the breathing patterns of healthy subjects using the Hexoskin smart shirt with integrated respiratory inductance plethysmography (RIP) sensors.

Study objective

To investigate the breathing patterns of asthma patients during exercise, compare this with the breathing pattern of healthy subjects and investigate whether the breathing pattern influences EID in patients with asthma.

Study design

The study will have an observational cross-sectional design. The study will compare the breathing pattern of asthma patients and healthy subjects during a VO2-max cycling ergometry test. Prior to the cycling ergometry test, salbutamol will be administered to the asthma patients to reduce the effect of EIB. The level of EIB will be objectified with lung function tests (Spirometry and forced oscillation technique (FOT).

Study burden and risks

The risk for adverse events due to participation in this study is minimal. Subjects will undergo measurements according to the standard protocol as used in clinical care. Because of the small risks concerning a VO2max cycling ergometry test, the subjects will be constantly monitored by a physician.

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

Asthma group:
- Confirmed asthma diagnosis by a health professional
- Patient using inhalaled corticosteroids
- Normal lung function under treatment (FEV1>80% predicted post salbutamol)
- Age 18-60

Healthy groep:
- No pulmonary disease
- No usage of lung related medication
- Age 18-60

Exclusion criteria

- Asthma exacerbation within 6 week before inclusion (asthma group only)
- More than 10 pack-years
- Pulmonary disease other than asthma
- Neurological or muscular disorder
- Meets one of the contra-indications mentioned in the cycling ergometry protocol from MST
- Has been tested postively for covid-19 in the past 3 months or has not fully recovered from an earlier covid-19 infection

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-04-2021
Enrollment:	108
Type:	Actual

Ethics review

Approved WMO

Date:	04-03-2021
Application type:	First submission
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

ID: 24296
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL75829.100.20
OMON	NL-OMON24296