The HexAs study: 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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24296

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Asthma

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The main study parameter is the breathing pattern of the subjects. The breathing pattern will be defined as follows: the breathing pattern describes the extent to which breathing frequency, tidal volume, abdominal breathing, and thoracic breathing contribute to the respiratory minute volume and how these change with different levels of physical exercise.

Secondary outcome

The secondary study parameters are parameters that might indicate the effects of the different breathing patterns. The level of dyspnoea is determined by the VAS and BORG score. EIB is a possible confounder, therefore, spirometry and FOT are done to investigate whether EIB is a contributor to possibly investigated dyspnoea.

Other parameters like the ACQ, mini-AQLQ, NQ, fat percentage, smoking status, frequency of physical exercise, medication use and the standard parameters measured during cycling ergometry are used to monitor whether other possible factors exist that affect the breathing pattern.

Study description

Background summary

90%van de astmapatiënten heeft last van inspanningsgeïnduceerde dyspnoe (Engels: exercíse induced
dyspnoea (EID). De meest voorkomende oorzaak hiervan is inspanningsgeïnduceerde bronchoconstrictie,
wat behandeld kan worden met medicatie. Ook een afwijkend ademhalingspatroon kan een van de
oorzaken zijn die leidt tot benauwdheid tijdens inspanning. Het ademhalingspatroon wordt gedefinieerd als
de bijdrage van teugvolume, ademfrequentie, buikademhaling en borstademhaling op het ademminuutvolume en hoe dit verandert als gevolg van inspanning. Echter, het ademhalingspatroon van
patiënten met astma is nooit goed in kaart gebracht, waardoor het onduidelijk is wat voor ademhalingspatronen astmapatiënten hebben tijdens inspanning, of dit afwijkt van de gezonde populatie
en of de mogelijke afwijking een oorzaak is van benauwdheid tijdens inspanning.
Dit leidt tot de hoofdvraagstelling:
"Wat is het ademhalingspatroon van patiënten met astma tijdens inspanning, hoe verschilt dit van het
ademhalingspatroon van gezonden tijdens inspanning en wat is de invloed van het

ademhalingspatroon op
de mate van inspanningsgéinduceerde dyspnoe."
Tijdens het onderzoek zullen proefpersonen enkele longfunctietesten ondergaan om de mate van
benauwdheid te meten, alsmede een V02-max fietstest. Tijdens deze metingen zullen de proefpersonen
een sportvest dragen met sensoren, die de ademhalingpatronen kunnen meten (het Hexoskin vest). Voor
het onderzoek zullen zowel patiënten met astma als gezonde proefpersonen geïncludeerd worden.

90% of asthma patients suffers from exercise induced dyspnoea (EID). Often, this is caused by exercise induced bronchoconstriction, which can be treated with medication. Additionally, an abnormal breathing pattern can also cause dypsnoea during exercise. The breathing pattern is defined as follows: the breathing pattern describes the extent to which breathing frequency, tidal volume, abdominal breathing, and thoracic breathing contribute to the respiratory minute volume and how these change with different levels of physical exercise. However, the breathing pattern of patients with asthma has never been adequately measured during exercise, therefore, it is unclear what the breathing pattern of asthma patients during exercise looks like and whether there is a difference with the breathing pattern of healthy subjects. This leads to the research question: “What is the breathing pattern of patients with asthma during exercise, how does this differ from the breathing pattern of healthy subjects during exercise and what is the influence of the breathing pattern on the level of exercise induced dyspnoea”.
In this study both patients with asthma and healthy subjects will be included. The subjects will undergo several lung function tests and a VO2-max cycling ergometry test to measure the level of dyspnoea and bronchoconstriction. During these measurements the subjects will wear a sports vest (Hexoskin) with integrated RIP-sensors which can measure the breathing pattern.

Study objective

The breathing pattern during exercise differs between asthma patients and healthy subjects.

Study design

T0, T1

Intervention

Spirometry, CO-diffusion, FOT, VO2-max cycling ergometry, questionnaires: ACQ, mini-AQLQ, Nijmegen questionnaire, VAS, BORG

Contacts

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Eligibility criteria

Inclusion criteria

Asthma group:
- Confirmed asthma diagnosis by a health professional
- Patient using ICS on daily basis
- Normal lung function under treatment (FEV1>80% predicted post salbutamol)
- Age 18-60
- Written informed consent prior to participation

Healthy group:
- No pulmonary disease
- No usage of lung related medication
- Age 18-60
- Written informed consent prior to participation

Exclusion criteria

- Has had an asthma exacerbation within 6 weeks before inclusion (asthma group only)
- More than 10 pack-years
- Pulmonary disease other than asthma
- No neurological or muscular disorder
- Not able to perform cycling ergometry.
- Does not fit one of the available Hexoskin shirts.
- Meets a contra-indication of the cycling ergometry protocol from the pulmonary department at MST (document: K6 protocol for cycling ergometry MST)
- Has been tested positively for COVID-19 in the past 3 months or has not fully recovered from an earlier COVID-19 infection

- Inability to read and/or understand the Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2021
Enrollment:	108
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-03-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50858
Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9310
CCMO	NL75829.100.20
OMON	NL-OMON50858

Study results