Telemonitoring for Asthma and COPD Through voICe AnalysiS: the TACTICAS study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27652

Source
Nationaal Trial Register

Brief title
TACTICAS

Health condition

asthma, COPD

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Boehringer Ingelheim, AstraZeneca

Intervention

Outcome measures

Primary outcome

To derive a digital fingerprint of dyspnoea in asthma and COPD by combining speech analysis as well as features extracted from spoken dialogue with daily dyspnea measurement as gold standard.

Secondary outcome

 To investigate if the digital dyspnoea fingerprint correlates with asthma and COPD severity.
 To investigate if the digital dyspnoea fingerprint in asthma and COPD correlates with quality of life.
 To investigate if the digital dyspnoea fingerprint in asthma and COPD correlates with physical activity.
 To investigate if the digital dyspnoea fingerprint in asthma and COPD correlates with exacerbation occurrence.
 To develop a patient interface consisting of a chatbot smartphone application plus wearable to objectively measure symptoms in an ecological momentary assessment.
 To develop a clinician dashboard that provides meaningful insight into the generated longitudinal patient data.
 To test feasibility and evaluate the system in a real-world outpatient care scenario with COPD and asthma patients.

Study description

Background summary

Rationale: Mobile health care technologies have the potential to help patients to manage their disease. These technologies have not yet been used to study symptoms in patients with respiratory diseases, such as asthma and COPD. We hypothesize that the quantification of the individual voice of patients with asthma and COPD is a way to capture and digitalise the respiratory discomfort experienced by these patients on a daily basis.
Objective: The primary objective is to investigate the correlation between acoustic speech characteristics and dyspnoea symptoms in patients with asthma and COPD. Secondary objectives are to correlate these acoustic speech characteristics with disease severity, quality of life, physical activity and exacerbations.
Study design: Prospective observational cohort study
Study population: Adults with asthma or COPD attending a university hospital outpatient clinic.
Intervention (if applicable): Three times a day, patients are prompted through a voice dialogue interface on their smartphone to perform speech tasks. Dyspnoea will be measured once daily via a short questionnaire.
Main study parameters/endpoints: Primary endpoint: (1) Difficulty in speech task, defined as the number of syllable per breath and (2) daily dyspnoea symptoms. Secondary endpoints: (1) Quality of life, (2) Physical activity level (3) Exacerbations

Study objective

We hypothesize that the quantification of the individual voice of patients with asthma and COPD is a way to capture and digitalise the respiratory discomfort experienced by these patients on a daily basis. Secondly, we hypothesize that we can capture acute exacerbations

of COPD using voice analysis.

Study design

baseline, daily scores for 12 weeks, week 12

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

- 18 years or older
- Physician diagnosed asthma or COPD: COPD is defined as subjects with an FEV1/FVC ratio of < 0.7 after bronchodilation. Asthma is defined as subjects with increased bronchial hyperreactivity measured with histamine provocation testing or subjects with a reversibility on spirometry. Reversibility is defined as a FEV1 or FVC response after bronchodilation of > 12% and > 200ml.
- Willingness and demonstration of ability to use a smartphone and fitness watch and to allow remote monitoring of vital signs.
- Able to understand, read and write Dutch language.

Exclusion criteria

- Exacerbation of asthma or COPD within 8 weeks of inclusion into the study

- Chronic respiratory insufficiency, defined as a resting pO2 < 8.0 kPa or pCO2 > 6.5 kPa, measured at sea level
- Co-morbidities that interfere with the registration or interpretation of symptoms, physical activity or quality of life, such as severe heart failure, interstitial lung diseases, or neuromuscular disorders.
- Persons who are dependent on others for activities of daily living.
- Persons who use a wheelchair or walker.
- Active malignancy.
- Expected life-expectancy less than 1 year.
- Investigator’s uncertainty about the willingness or ability of the patient to comply with the protocol requirements.
- Participation in another study involving (non)-investigational products.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-05-2021
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9360
Other	MET AzM/UM : METC azM/UM-NL76219.068.20/METC 21-001

Study results