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

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27652

Bron
NTR

Verkorte titel
TACTICAS

Aandoening

asthma, COPD

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: Boehringer Ingelheim, AstraZeneca

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

baseline, daily scores for 12 weeks, week 12

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

Maastricht University
Sami Simons

0433877043

Wetenschappelijk

Maastricht University
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0433877043

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	03-05-2021
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9360
Ander register	MET AzM/UM : METC azM/UM-NL76219.068.20/METC 21-001

Resultaten