Assessment of the Usability and Feasibility of a Breath-based Home-monitoring Tool for Asthma, CF, COPD and PCD Disease Stability

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Main Objective:To assess the feasibility and usability of the PHEASANT device as a home-monitoring tool across diverse age groups and pulmonary diseases, including asthma, cystic fibrosis (CF), primary ciliary dyskinesia (PCD), and chronic…

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory tract infections
Study type	Observational non invasive

Summary

ID

NL-OMON57546

Source
ToetsingOnline

Brief title
PHEASANT Study

Condition

- Respiratory tract infections

Synonym
Chronic lung diseases (asthma, cystic fibrosis, primary ciliary dyskinesia and chronic obstructive pulmonary disease)

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Amsterdam UMC,Boehringer Ingelheim,Stichting TAAI;Stichting Asthma Bestrijding (SAB),Vertex Pharmaceuticals

Intervention

Keyword: Chronic lung diseases, eNose (electroonic nose), Exhaled breath, Home-monitoring

Outcome measures

Primary outcome

Main study parameter/endpoint:

- Feasibility and usability assessment by User Experience Questionnaires (UEQs)

- PHEASANT experiences by semi-structured interview

Secondary outcome

Secondary study parameters/endpoints:

- Food intake by food diary

- Respiratory disease symptoms: fatigue and dyspnoea (by VAS)

- Environmental conditions: humidity, temperature and air pressure

Other parameters:

- Patient demographics (gender, age, weight, height education etc.)

- Disease information (diagnosis, symptoms, medication use etc.)

Study description

Background summary

Chronic pulmonary diseases like asthma, cystic fibrosis (CF), primary ciliary

dyskinesia (PCD), and chronic obstructive pulmonary disease (COPD) impose a substantial healthcare burden due to delayed detection and treatment of respiratory symptoms. Early detection and intervention are critical for preserving lung function and enhancing quality of life. However, current clinic-based monitoring methods may miss subtle changes, necessitating innovative approaches. Home-monitoring of exhaled breath holds promise for improving early detection and management of exacerbations, ultimately improving patient outcomes. This study aims to evaluate the feasibility and usability of such breath-based monitoring tool, the PHEASANT device, in real-world settings to address the user experience of this device in different populations. Additionally, it seeks to enhance understanding of factors influencing device performance and informing its potential integration into routine clinical practice.

Study objective

Main Objective:
To assess the feasibility and usability of the PHEASANT device as a home-monitoring tool across diverse age groups and pulmonary diseases, including asthma, cystic fibrosis (CF), primary ciliary dyskinesia (PCD), and chronic obstructive pulmonary disease (COPD).

Secondary Objectives:
To investigate factors that may influence PHEASANT measurements, including food intake, environmental conditions (humidity, temperature, air pressure), device placement within the household, and airway symptoms of the patients.
To evaluate the user experience of the PHEASANT device among individuals with chronic pulmonary diseases, including satisfaction with device usability, comfort, and convenience.
To gather feedback from participants regarding their experiences with using the PHEASANT device and participating in home-based monitoring, including suggestions for improvement.

Study design

The design of the study can be described as a longitudinal prospective observational cohort investigation.

Study burden and risks

Participation in the study involves two visits at the patient*s home; one to start the study period and a the second visit, after two weeks, to conclude the study period by means of a semi-structured interview. Moreover, the study involves daily usage of the PHEASANT device (11 days just once, 3 days six times), completing questionnaires on symptoms (two questions a day) and dietary intake (on 3 days only).

There are no benefits of participating in this study. Additionally, there are no disadvantages for participants either, except for the time required to perform the measurements with the PHEASANT and complete the questionnaires. The risks of participating in this study are negligible.

Contacts

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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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
Being six years of age or older

and
Asthma diagnosis is based on: clinical symptoms in combination with treatment according to the 2023 Global Initiative for Asthma (GINA) classification 2 or higher.
or
CF diagnosis is based on: clinical symptoms in combination with an abnormal sweat test (chloride > 60 mmol/l) and/or identification of mutations in both alleles of the CFTR gene.
or
PCD diagnosis is based on: a combination of clinical symptoms, abnormal movement of cilia on microscopic evaluation of respiratory epithelial biopsies and epithelial cell cultures, or identification of an ultra-structural defect in the cilia by electron microscopy.
or
COPD diagnosis is based on a: a combination of clinical symptoms as described in the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines AND forced spirometry showing the presence of a post-bronchodilator FEV1/FVC < 0.7.
and
Dutch speaking

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
If they have insufficient understanding of the Dutch language to fill out the study questionnaires
If they have such severe pulmonary symptoms that they are admitted to a hospital or care facility or need continuous oxygen administration. As this may limit their ability to use the PHEASANT.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	65
Type:	Anticipated

Medical products/devices used

Generic name:	PHEASANT
Registration:	No

Ethics review

Approved WMO

Date:	13-05-2025
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL86911.018.24