Standardized dietary challenge to monitor effects of rehabilitation program in patients with COPD: a pilot study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON54507

Source
ToetsingOnline

Brief title
Dietary challenge in COPD

Condition

- Appetite and general nutritional disorders
- Respiratory disorders NEC

Synonym
COPD, emphysema and chronic bronchits

Research involving
Human

Sponsors and support

Primary sponsor: CIRO
Source(s) of monetary or material Support: Ciro en Kennisinstituut TNO

Intervention

Keyword: COPD, Dietary challenge, Phenflex, pulmonary rehabilitation

Outcome measures

Primary outcome

The main study parameter is to explore if there is an association between the pulmonary rehabilitation and the *metabolic age* or metabolic resilience, measured with the composite biomarker. The composite biomarker is based on blood response curves (t=0, 30, 60, 120 and 240 minutes) of six blood parameters after consumption of the PhenFlex drink: glucose, C-peptide, non-esterified fatty acids, cholesterol, HDL-cholesterol, triglycerides. The parameters are measured in blood. The composite biomarker will be reported as a health score, which is calculated by combining the outcome of the separate measures.

Secondary outcome

To explore associations between the metabolic resilience and the change in the above described biomarkers after pulmonary rehabilitation. Moreover, the change in the regular outcomes of pulmonary rehabilitation will be studied: health status (using the COPD Assessment Test (CAT)), mood status (using the Hospital Anxiety and Depression Scale (HADS)), exercise performance (using the cardiopulmonary exercise tests (CPET) (only at baseline), 6-min walk distance (6 MWT) and constant work rate cycling test (CWRT)), muscle strength and endurance (using the BIODEX computerized dynamometer), degree of symptoms (using the modified Medical Research Council (mMRC) dyspnea grade and the Checklist Individual Strength (CIS) fatigue domain), resting blood pressure

measures (systolic and diastolic blood pressure), and body composition (with focus on body weight, waist circumference, fat-free mass and fat mass using DXA scanning). To explore associations between the change in phenotypic flexibility of COPD patients before and after rehabilitation and variables associated with phenotypic flexibility will also be studied: lifestyle measured with the lifestyle and health questionnaire, food intake measured by the Eetscore questionnaire, and optional stress with hair cortisol levels. The validity of continuous vital sign monitoring by a non-invasive health patch in COPD patients shall be evaluated.

Study description

Background summary

Chronic obstructive pulmonary disease (COPD) is primary a chronic respiratory disease characterized by persistent airflow limitation. However, COPD is today recognized as a systemic disease with multiple co-morbidities and extra-pulmonary features. Indeed, patients with COPD suffer more from alterations in body composition, osteoporosis and hyperglycaemia compared to an age-matched control group (Triest et al. unpublished data). Furthermore, about 30% of the patients with COPD have continuous low-grade systemic inflammation. Due to the parallelism between the progression of COPD and the ageing process, it has been proposed that COPD can be a syndrome of accelerated ageing. Based on telomere length, a COPD patient has a biological age of on average 8 years older compared to a control subject with the same age. From this point of view, it is reasonable to hypothesis that the metabolic flexibility of a patient with COPD is different compared to an age-matched healthy peer.

In nutrition and health research, there is a growing awareness that health is determined by the ability to maintain or regain homeostasis after various physiologic stresses and that this characteristic can be used to study and quantify the effects of nutrients or nutrition on multiple aspects of health. In a recent study, the WHO definition of health originating from 1948 is reconsidered and redefined as *the resilience of homeostatic control*: the ability to cope with daily challenges without drifting out the regulated homeostatic/allostatic zone. In short, this concept describes health as *an

ability to adapt* to various day-to-day challenges (e.g. strenuous exercise or dietary challenge). Pulmonary rehabilitation may change the resilience of homeostatic control.

Study objective

In the present pilot study, we intend to test phenotypic flexibility (Phenflex) in 20 clinically stable patients with COPD by exploring their response to a dietary challenge test before and after pulmonary rehabilitation. Moreover, the baseline results of the present pilot study will be compared with the results of the control subjects obtained in study CHDR1230, in which 100 female and male subjects within the ranges of a healthy population were measured and with 20 male type 2 diabetic subjects that participated in study CHDR1211. This pilot study aims also to explore phenotypic flexibility of COPD patients before and after pulmonary rehabilitation, as pulmonary rehabilitation is expected to have a positive effect of patients* health.

Study design

The study is a single center, explorative observational pilot study with a dietary challenge test before and after rehabilitation

Intervention

During the test day before and after pulmonary rehabilitation a high calorie dietary challenge drink, the so called Phenflex drink will be administered to all volunteers. This 500 mL drink contains 75 g glucose, 20 g Protifar (Nutricia), 60 g palm oil, flavour and 345 mL water.

Study burden and risks

The total engery intake of 900 kcal at once cold cause a feeling of nausea or abdominal bloating. To reduce the already minimal potential risk, subject with a reported food allergy or sensitivity for one of the used ingredients will be excluded from study participation. Due to the long fasting period, the patient can feel dizzy or have headach. Inserting a cannula can be painful and a bruise can be a consequence of the cannula.
The health patch may cause irritation of the skin in some individuals. If participants experience irritation caused by the health patch, the health patch will be removed but the participants can continue with the study.

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

- Objective diagnosis of COPD
- Approval for a pulmonary rehabilitation program (inpatient or outpatient) of Ciro after start assessment

Exclusion criteria

- Clinically important pulmonary disease other than COPD
- Participation in an investigational drug within 3 months prior to screening.
- Unacceptable concomitant medication use at baseline, e.g., drugs known or likely to interact with the challenge drink or study assessments.
- Reported food allergy or sensitivity for one of the used ingredients of the Phenflex shake

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-06-2023
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	health patch
Registration:	No

Ethics review

Approved WMO Date:	02-12-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-08-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-12-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	

Date:	11-03-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	15-11-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-03-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-11-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-01-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-05-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	11-07-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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: 26982
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL62032.028.19
Other	Trial NL7793