‘Standardized dietary challenge in patients with COPD: a pilot study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26982

Source
NTR

Brief title
Dietary challenge in COPD

Health condition

COPD

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

What is the phenotypic flexibility of COPD patients before and after a comprehensive pulmonary rehabilitation program?

Secondary outcome

• To compare the phenotypic flexibility of COPD patients with the pre-obtained phenotypic flexibility of a healthy population and to diabetic type 2 patients;
• To compare the phenotypic flexibility of COPD patients with lean body composition and metabolic syndrome before and after rehabilitation;
• To explore associations between the phenotypic flexibility of COPD patients within the regular outcomes of pulmonary rehabilitation and the changes in these outcomes:
o health status, assessed with the COPD Assessment Test
o mood status, assessed with the Hospital Anxiety and Depression Scale
o physical performance, assessed with the 6-minute walk distance and a constant work rate cycling test (75% of the pre-determined peak cycling output), quadriceps peak torque and endurance assessed on a computerized dynamometer
o symptoms, assesses with the modified MRC dyspnoea scale (dyspnoea) and the fatigue domain of the Checklist Individual Strength (fatigue)
o body composition, assessed with a whole-body and local DEXA scan
• To explore associations between the change in phenotypic flexibility of COPD patients before and after rehabilitation and variables associated with phenotypic flexibility:
o lifestyle measured with the lifestyle and health questionnaire
o food intake measured by the Eetscore questionnaire
o stress, assessed with hair cortisol levels.

Study description

Background summary

Rationale: Chronic obstructive pulmonary disease (COPD) is a systemic disease affecting different parts of the body. It is not clear how the metabolic flexibility is affected in patients with COPD.
Objective: To investigate phenotypic flexibility in response to a high calorie challenge drink in patients with COPD before and after an 8-week inpatient pulmonary rehabilitation.
Study design: Single-centre, explorative intervention pilot study.
Study population: 20 clinically stable patients with COPD (n=10 with a lean body composition and n=10 with metabolic syndrome).
Intervention (if applicable): The patients will undergo a routine comprehensive pulmonary rehabilitation program at CIRO. This is standard care, no experimental intervention.
Main study parameters/endpoints: To evaluate the efficacy of a standard comprehensive pulmonary rehabilitation program in lean COPD patients and COPD patients with metabolic syndrome, by examining a ‘metabolic age’ composite biomarker. The composite biomarker contains multiple blood markers of multiple time points after a PhenFlex challenge drink. The PhenFlex challenge drink is a method used to evaluate ‘health’: metabolic resilience after a metabolic challenge. The metabolic health and metabolites measured by metabolomics technology and the change in these biomarkers may be altered due to pulmonary rehabilitation and perhaps be different in lean COPD patients compared to COPD patients with metabolic syndrome at baseline.
Nature and extent of the burden and risks associated with participation, benefit and group

relatedness: The volunteers will ingest before and after a pulmonary rehabilitation program a high caloric challenge drink of 500 mL, containing 75 g glucose, 20 g Protifar (Nutricia), 60 g palm oleine and 320 ml water and 0.5 g artificial aroma at fasting condition. Since this high caloric challenge drink consists of commonly used food nutrients, it is expected to be safe. Immediately before (t = 0 m) and at standardized time points after the administration (t = 0.5h, 1h, 2h, and 4h), blood samples will be collected. The standard, comprehensive pulmonary rehabilitation program is expected to improve daily symptoms, exercise performance and quality of life in patients with COPD. There is no additional benefit for the volunteers participating in this pilot, as the care provided is standard care.

Study objective

to test phenotypic flexibility (Phenflex) in 20 clinically stable patients with COPD by examining their response to a dietary challenge test before and after pulmonary rehabilitation.

Study design

In may 2019 the protocol will be submitted to an acknowlegde medical ethical committee in the Netherlands.

Intervention

The regular rehabilitation program in Ciro and network consists of a baseline assessment (duration: 3 days), rehabilitation program (duration: 5 days per week, 8 weeks) and an outcome assessment (duration: 2 days). Patients will be asked to come an extra day to Ciro before the rehabilitation and after the outcome assessment for a test day to ingest the Phenflex drink and the additional measurements.

Contacts

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Eligibility criteria

Inclusion criteria

- Objective diagnosis of COPD
- Males
- Age range from 40-59 year
- No carcinogenic events for the last 5 years
- Capability to read and understand the study protocol
- N=10 lean body composition: BMI between 20 and 25 kg/m2 with a normal FFMI (> percentile 5 according to Franssen et al.) and without metabolic syndrome).
- N=10 with metabolic syndrome according to international criteria.

Exclusion criteria

- Clinically important pulmonary disease other than COPD (e.g. but not limited to active lung infection, clinically significant bronchiectasis, pulmonary fibrosis, lung cancer, asthma as primary or main diagnosis) or other pulmonary disorder as judged by the Investigator.
- An increase in complaints of the lungs defined by a physician as an exacerbation COPD within 4 weeks of the routine baseline assessment and between the period of routine baseline assessment and the first test day.
- Participation in an investigational drug within 3 months prior to screening.
- Loss of blood outside the limits of Sanquin (500 mL) within 3 months prior to screening or not willing to refrain from blood- or plasma donation during the study.
- Average alcohol consumption > 21 units/week.
- Unacceptable concomitant medication use at baseline, e.g., drugs known or likely to interact with the challenge drink or study assessments.
o Use of non-steroidal anti-inflammatory drugs (NSAIDs) (i.e. ibuprofen, aspirin), statins, and beta-blockers is not allowed during the evening before and during the test days. Patients are eligible after approval by the doctor to stop the abovementioned medication the evening before and during the nutritional challenge test days.
- Reported food allergy or sensitivity for one of the used ingredients of the Phenflex shake.
- Not willing to accept information transfer which concerns participation in the study or information regarding health (e.g. laboratory results, findings at health and lifestyle questionnaire, physical examination or eventual adverse events) to and from their general practitioner.
- Unintentional weight loss or gain > 5% body weight in the last month.
- Clinically significant abnormalities, as judged by the investigator, in laboratory test results. In the case of uncertain or questionable results, tests performed during screening may be repeated once before determination of eligibility. This will be judged by the physician.
- Inappropriate veins for cannula insertion.
- Having a chronic auto-immune disease (such as arthritis).
- Having a history or symptoms of any significant disease including (but not limited to),

neurological, psychiatric, endocrine, gastrointestinal, hepatic, or renal disorder.
- Unwillingness or inability to comply with the study protocol for any other reason.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2019
Enrollment:	10
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

ID: 54507
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7793
CCMO	NL62032.028.19
OMON	NL-OMON54507

Study results