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

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26982

Bron
NTR

Verkorte titel
Dietary challenge in COPD

Aandoening

COPD

Ondersteuning

Primaire sponsor: Ciro
Overige ondersteuning: Ciro and Kennisinstituut TNO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Ciro
Miriam Groenen

+31 475 587650

Wetenschappelijk

Ciro
Miriam Groenen

+31 475 587650

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2019
Aantal proefpersonen:	10
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

ID: 54507
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten