The effect of targeted nutrient supplementation on physical activity and health related quality of life in COPD

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON52907

Source
ToetsingOnline

Brief title
NUTRECOVER trial

Condition

- Muscle disorders
- Cognitive and attention disorders and disturbances
- Bronchial disorders (excl neoplasms)

Synonym
Chronic obstructive pulmonary disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Longfonds

Intervention

Keyword: COPD, Health related quality of life, Nutrient supplementation, Physical activity

Outcome measures

Primary outcome

- Physical activity level

- General health status

Secondary outcome

- Mental health

- Physical performance

- Blood markers

- Patient related outcomes

- Gut health

Study description

Background summary

Impaired physical and mental health are common features in COPD adversely affecting disease course and quality of life. Furthermore, nutritional status is often impaired due to dietary and plasma nutrient deficiencies, decreased muscle oxidative metabolism and impaired intestinal permeability. We hypothesize that targeted nutrient supplementation can lead to gut-muscle-brain axis-mediated amelioration of physical, cognitive and mental health domains, resulting in a healthier lifestyle, in moderate to very severe COPD patients.

Study objective

To investigate the efficacy of targeted nutrient supplementation on daily physical activity level as well as generic health status in patients with moderate to very severe COPD. Additionally, we aim to disentangle the relative effect of targeted nutrient supplementation on the recovery after

hospitalization for a COPD exacerbation. Furthermore, we want to investigate if the gut microbiome composition in patients with COPD is disrupted in comparison with a reference group at baseline and if the composition improves after 3 months of nutritional intervention (in COPD patients only).

Study design

Randomized, placebo-controlled, double-blind trial comparing two groups of 83 patients.

Intervention

The intervention group will receive 1 supplement per day for at least 12 months. The main components of the supplement are vitamin D, tryptophan, long-chain polyunsaturated fatty acids (PUFA), and fibres. The control group will receive an isocaloric placebo for at least 12 months. In addition, both groups will receive counselling on medical adherence, healthy lifestyle and management of weight loss over the course of the study.

Study burden and risks

The nutrient supplement is hypothesized to have beneficial effects on general health because it applies physical and mental health domains. The healthy lifestyle counselling aims to improve medical adherence, to address a healthier lifestyle and to manage weight loss which would contribute to improved general health. Risks and inconveniences are limited to the time investment associated with taking the supplements and measuring days. During the test-days various non-invasive measurements as well as minor invasive blood sampling will be performed. We expect no risk of the nutrient supplementation.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P Debyelaan 25
Maastricht 6202 AZ
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P Debyelaan 25
Maastricht 6202 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

COPD patients NUTRECOVER trial:

- COPD patients with moderate to very severe disease stage according to GOLD criteria (i.e. GOLD stage II-IV);
- Medically stable in the opinion of the investigator.

Reference group microbiome study:

- Lung function: FEV1/FVC > 0.7
- Medically stable in the opinion of the investigator.

Exclusion criteria

COPD patients NUTRECOVER trial:
Exclusion criteria indicated with an asterisk (*) are also exclusion criteria for the subjects in the reference group for the microbiome study.

- Age <18 years;*
- Allergy or intolerance to components of the study product;
- Investigator*s uncertainty about the willingness or ability of the patient to comply with the protocol requirements (e.g. leg amputation) or patients suffering from other acute or unstable chronic diseases that will compromise the study outcome (e.g. active cancer requiring treatment);*
- Participation in any other study involving investigational or marketed products concomitantly or within four weeks prior to entry into the study;*
- Patients with terminal illness;*
- Recent hospital admission (<4 weeks prior to the start of the study);*
- COPD patients with temporary oral steroid or antibiotics use due to a COPD

exacerbation in the last 4 weeks or subjects in the reference group with antibiotics use for any reason in the last 4 weeks;
- Lung malignancy in the previous 5 years;*
- Diagnosis of dementia or neurodegenerative disease (e.g., Alzheimer*s disease, Parkinson*s disease, Huntington*s chorea, frontotemporal dementia) in the medical records;*
- Recent diagnosis of cerebral conditions (< 1 year e.g. cerebral infarction, hemorrhage, brain tumors, transient ischemic attack) in the medical records;*
- Any medical condition that significantly interferes with digestion and/or gastro-intestinal function (e.g. short bowel syndrome, inflammatory bowel disease, gastric ulcers, gastritis, (gastro)-enteritis, GI cancer as judged by the investigator;*
-Subjects in the reference group in the microbiome study: diagnosis of any chronic lung disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-02-2020
Enrollment:	198
Type:	Actual

Ethics review

Approved WMO

Date:	13-01-2020

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-10-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT03807310
CCMO	NL66543.068.18