Beta-alanine supplementation in patients with COPD receiving non-linear periodized exercise (NLPE) training: randomized placebo-controlled trial.

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It is hypothesized that beta-alanine supplementation in patients with COPD following a non-linear periodized exercise (NLPE) training program (as part of pulmonary rehabilitation; PR) will increase muscle carnosine levels, which in turn will result...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23943

Bron
Nationaal Trial Register

Verkorte titel
BASE-TRAIN

Aandoening

Chronic obstructive pulmonary disease (COPD); Exercise intolerance; Muscle dysfunction.

Ondersteuning

Primaire sponsor: Radboudumc Board of Directors
Overige ondersteuning: Lung Foundation, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Exercise tolerance, defined as walk endurance time. This will be assessed via the endurance shuttle walk test, a standardized externally controlled constant paced field test at 85% of the pre-determined maximal velocity (evaluated by the incremental shuttle walk test) until exhaustion.

Toelichting onderzoek

Achtergrond van het onderzoek

Exercise intolerance is common in patients with chronic obstructive pulmonary disease (COPD) and, although multifactorial, it is largely caused by lower-limb muscle dysfunction. Research has shown that patients with severe to very severe COPD have significantly lower levels of muscle carnosine, which acts as a pH buffer and antioxidant. Beta-alanine (BA) is the rate-limiting precursor to carnosine synthesis and BA supplementation has been shown to consistently elevate muscle carnosine in a variety of populations. Hence, it is very plausible to hypothesize that BA supplementation in COPD patients following a non-linear periodized exercise (NLPE) training program (as part of pulmonary rehabilitation; PR) will increase muscle carnosine levels, which in turn will result in a positive effect on exercise tolerance and lower-limb muscle function.

Doel van het onderzoek

It is hypothesized that beta-alanine supplementation in patients with COPD following a non-linear periodized exercise (NLPE) training program (as part of pulmonary rehabilitation; PR) will increase muscle carnosine levels, which in turn will result in a positive effect on exercise tolerance and lower-limb muscle function. These adaptations may translate into improved functional capacity during activities of daily living and improved quality of life. The primary targets of both exercise training and BA supplementation are the muscles of ambulation. Nevertheless, it seems reasonable to hypothesize that an enhanced bio-availability of carnosine in the body, by means of beta-alanine supplementation, may have an anti-oxidative effect in both the muscle and the brain.

Onderzoeksopzet

The regular PR program at CIRO and Dekkerswald consists of a baseline assessment, followed by an in- or outpatient PR program and is ended with a post-rehabilitation assessment. After completion of the baseline assessment and obtaining informed consent, an additional study-related appointment is scheduled with included patients approximately 1-2 week prior to the start of the PR program. This additional testing day will be repeated after the rehabilitation

period. Study duration per subject will be approximately 10 to 12 weeks. During the regular (baseline and post) assessments, the following outcomes will be measured: exercise capacity, tolerance and endurance, quadriceps muscle function, body composition, physical activity, dyspnoea, health-related quality of life, anxiety and depression, fatigue, pulmonary function and patient characteristics. The study-related appointments include: fasting venous blood sampling, a vastus lateralis muscle biopsy (optional, not required) and two cognitive function tests (M-WCST and SCWT). During the PR program the patients will receive NLPE as standard care. Patient safety and compliance will be constantly monitored during the PR program.

Onderzoeksproduct en/of interventie

Oral beta-alanine (sustained-release Carnosyn®; 3.2 g/day) or identical looking placebo supplementation for a duration of 8-10 weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- COPD, GOLD group B or D
- Modified Medical Research Council (mMRC) dyspnoea score ≥2
- Clinically stable according to the pulmonary physician, i.e. no exacerbation and/or hospitalization within the previous 4 weeks.

- Age between 40-80 years
- Attending the regular in- or outpatient pulmonary rehabilitation program in Dekkerswald or CIRO and receiving NPLE

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients will be excluded if they meet at least one of the following criteria: instable cardiac disease, use of anabolic steroids during PR program, history of drugs/alcohol abuse, vegetarianism, inability to understand the Dutch language, self-reported beta-alanine supplementation in the past 3 months, participation in a PR program within the past 12 months, inability to perform an incremental shuttle walk test.

If the patient agrees to undergo a vastus lateralis muscle biopsy, the following exclusion criterion will also apply: bleeding disorder, a recent trauma of the muscle, or an infection in the region of the proposed biopsy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2020
Aantal proefpersonen:	154
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-03-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49690
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8427
CCMO	NL70781.091.19
OMON	NL-OMON49690

Resultaten