Beta-Alanine Supplementation in patients with COPD following an exercise training program to strengthen the lower limbs.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON56353

Source
ToetsingOnline

Brief title
BASE-ELECTRIC

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic obstructive pulmonary disease; chronic lungdisease with persistent obstruction of the airways

Research involving
Human

Sponsors and support

Primary sponsor: CIRO
Source(s) of monetary or material Support: Longfonds Nederland

Intervention

Keyword: Beta-Alanine supplementation, Chronic obstructive, Neuromuscular Electrical stimulation, Pulmonary disease, Pulmonary Rehabilitation

Outcome measures

Primary outcome

Exercise tolerance, defined as the change in cycle endurance time (before and after the rehabilitation period), measured during a constant work rate cycle test (CWRT)

Secondary outcome

Lower-limb muscle function, 6-minute walking distance, fatigue, disease specific quality of life, body composition, dyspnoea, symptoms of anxiety and depression, physical activity, problematic activities of daily life, mobility, cognitive function, respiratory muscle strength, systemic beta-alanine, carnosine, taurine and histidine, systemic inflammatory and oxidative stress markers, muscle beta-alanine, carnosine, taurine and histidine, muscle inflammation and oxidative stress and inflammatory and oxidative stress markers in the lungs, therapy adherence, patient safety and supplement duration.

Study description

Background summary

Physical inactivity and oxidative stress have been identified as the two main causes of reduced quadriceps muscle strength and endurance, two well-known

disabling extra-pulmonary features in patients with COPD. In healthy untrained elderly subjects, oral beta-alanine supplementation (without training) is powerful in increasing muscle carnosine content and exercise capacity by 13-29%. It is very plausible to hypothesize that increased muscle carnosine levels will have a positive effect on lower-limb muscle function and exercise tolerance in COPD, by buffering pH and scavenging Reactive Oxygen Species (ROS). To date, neuromuscular electrical stimulation (NMES) is one of the best strategies to improve lower-limb muscle function and exercise tolerance in COPD patients with explicit functional limitations and high symptom burden. These patients also receive resistance training 1-2 times per day, as part of standard care to further improve lower-limb muscle function and exercise tolerance. Beta-alanine supplementation is expected to augment the effects of NMES-based pulmonary rehabilitation on exercise tolerance, lower-limb muscle function, oxidative stress, fatigue, physical activity, and quality of life in COPD patients.

Study objective

The primary objective is to compare the effects of daily beta-alanine supplementation or a placebo supplement on exercise tolerance (cycle endurance time).
The secondary objectives are:
1) To compare the effects of daily oral beta-alanine supplementation or a placebo supplement in patients with COPD on: lower-limb muscle function, 6-minute walking distance, fatigue, disease specific quality of life, body composition, dyspnoea, symptoms of anxiety and depression, physical activity, problematic activities of daily life, mobility, cognitive function, respiratory muscle strength, systemic beta-alanine, carnosine, taurine and histidine, systemic inflammatory and oxidative stress markers, muscle beta-alanine, carnosine, taurine and histidine, muscle inflammation and oxidative stress, inflammatory and oxidative stress markers in the lungs, patient safety and therapy adherence.
2) To evaluate whether there is a correlation between changes in muscle beta-alanine/carnosine levels and changes in exercise tolerance, lower-limb muscle function, systemic inflammatory and oxidative stress markers, muscle inflammation and oxidative stress, inflammatory and oxidative stress markers in the lungs.

Study design

Prospective, randomized, double-blind, placebo-controlled study

Intervention

Oral beta-alanine supplementation (sustained-release Carnosyn®; 3.2 g/day) or

placebo for 8-10 weeks.

Study burden and risks

BURDEN: In addition to standard care (NMES and resistance training, as part of regular pulmonary rehabilitation program at CIRO), participants are asked to perform additional measurements (venous blood sampling, vastus lateralis muscle biopsy (optional, not required), cognitive function tests (M-WCST and SCWT), and pulmonary function tests (NO-measurement) on 2 separate days in total (1 before intervention and 1 after intervention). Furthermore, participants have to take supplements on a daily basis for 8-10 weeks.
RISKS: The proposed dose of sustained release beta-alanine (SR Carnosyn®; 3.2 g/day) is proven effective, without any side-effects. Complications of vastus lateralis muscle biopsy may include infection, bleeding and hematoma formation. These complications are rare (<1.5%) if the test is performed properly under semi-sterile conditions. Venous blood sampling is associated with a 5% risk of developing local haemorrhage. However, this will disappear within 2 weeks and is not associated with (functional) limitations.
BENEFIT: Irrespective of treatment allocation, both groups will benefit from participating in the pulmonary rehabilitation program. Beta-alanine is known to be effective in increasing muscle carnosine content in both healthy young adults and elderly subjects, with subsequent improvement in their exercise tolerance and has the potential to reduce oxidative stress and improve cognitive function.
GROUP RELATEDNESS: This will be the first study in which oral beta-alanine supplementation will be combined with a pulmonary rehabilitation program in COPD patients

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

- COPD, GOLD group B or D (high symptomatic)
- Grade 3 or higher on the Modified Medical Research Council (mMRC) dyspnoea scale
- Clinically stable according to the pulmonary physician, i.e. no exacerbation and/or hospitalization within the previous 4 weeks.
- Age between 40-80 years
- Cycle endurance time, measured during a constant work rate test (CWRT) at 75% of the peak cycling load, is 100-300 seconds and/or Quadriceps Muscle Strength (peak torque), measured with a computerized dynamometer, is less than 80% of the predicted value
- Attending the regular inpatient pulmonary rehabilitation program in CIRO and receiving NMES as the primary muscle training modality.
- No use of anabolic steroids during the inpatient pulmonary rehabilitation program in CIRO

Exclusion criteria

- Instable cardiac disease
- Neurological disease and/or musculoskeletal disease that preclude safe participation in an exercise test
- History of drugs/alcohol abuse in the past 10 years
- Vegetarianism
- Inability to understand the Dutch language
- Self-reported β-alanine supplementation in the past 3 months
- Participation in pulmonary rehabilitation within the past 12 months

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):	12-09-2023
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO Date:	12-02-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-06-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-09-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-02-2024
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-05-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-06-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 25510
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68757.091.19