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

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON49690

Source
ToetsingOnline

Brief title
BASE-TRAIN

Condition

- Bronchial disorders (excl neoplasms)

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

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Longfonds Nederland

Intervention

Keyword: Beta-Alanine supplementation, Chronic Obstructive Pulmonary Disease, Non-linear periodized exercise training, Pulmonary Rehabilitation

Outcome measures

Primary outcome

The primary study parameter is exercise tolerance, determined with the

endurance shuttle walk test as the walking endurance time.

Secondary outcome

The secondary study parameters are cycle endurance time, lower-limb muscle

function, muscle and systemic carnosine, taurine, beta-alanine and histidine,

muscle and systemic oxidative stress and inflammation, dyspnoea, fatigue,

physical activity, symptoms of anxiety and depression, body composition,

cognitive function, respiratory muscle strength and disease-specific quality of

life. Furthermore, the therapy adherence and patient safety will be assessed.

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 Chronic Obstructive Pulmonary Disease (COPD). In healthy untrained elderly subjects, oral beta-alanine supplementation (without exercise 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, non-linear periodized exercise (NLPE) training 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. Beta-alanine supplementation is expected to augment the effects of exercise-based rehabilitation on lower-limb muscle function, exercise tolerance, 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 (walking endurance time) in patients with COPD receiving NLPE.
The secondary objectives are:
• to determine the effects of beta-alanine supplementation in patients with COPD receiving NLPE on cycle endurance time, lower-limb muscle function, muscle and systemic carnosine, taurine, beta-alanine and histidine, muscle and systemic oxidative stress and inflammation, fatigue, dyspnoea, symptoms of anxiety and depression, body composition, physical activity, cognitive function, respiratory muscle strength, disease-specific quality of life and patient safety and therapy adherence.
• to evaluate the correlation between the change in carnosine levels and change in exercise tolerance, lower-limb muscle function and oxidative stress and inflammation after 8 weeks of daily oral beta-alanine supplementation in patients with COPD receiving NLPE.

Study design

Prospective, randomized, double-blind, placebo-controlled, multi-centre 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 (NLPE as part of regular pulmonary rehabilitation program at Dekkerswald and CIRO), participants are asked to perform additional measurements (venous blood sampling, muscle biopsy and 2 cognitive function tests) on 2 separate days (1 day before and 1 day after the rehabilitation). 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 in healthy adults and elderly, 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 capacity and has the potential to reduce oxidative stress and improve cognitive function. So combining exercise-based rehabilitation with beta-alanine supplementation has the potential to increase exercise tolerance and quality of life of patients with COPD to a greater extent than exercise training alone.
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

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. COPD group B or D (high symptomatic)
2. Grade 2 or higher on the modified Medical Medical Research Council (mMRC)
3. Clinically stable on the basis of clinical picture by pulmonary physician, i.e. no exacerbation and/or hospitalization within the previous 4 weeks
4. Age between 40-80 years
5. Attending the regular rehabilitation program in Dekkerswald or CIRO and receiving NLPE.
6. No use of anabolic steroids during the inpatient pulmonary rehabilitation program in Dekkerswald and CIRO.

Exclusion criteria

1. Instable cardiac disease.
2. Participants treated with Neuromuscular Eletrical Stimulation (NMES)
3. History of drugs/alcohol abuse
4. Vegetarianism
5. Inability to understand the Dutch language
6. Self-reported beta-alanine supplementation in the past 3 months (wash-out period is set at 9 weeks).
7. Participation in pulmonary rehabilitation within the past 12 months.
8. Inability to perform the incremental shuttle walk test

If the patient agrees to undergo a muscle biopsy, the following exclusion criterion will also apply:
9. Patients with bleeding disorders, a recent trauma of the muscle or an infection in the region of the proposed biopsy will be excluded for the muscle biopsies.

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:	Will not start
Enrollment:	154
Type:	Anticipated

Ethics review

Approved WMO Date:	17-02-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-03-2020
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: 23943
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70781.091.19
OMON	NL-OMON23943