

Reduction of OXidative stress in Chronic Obstructive Pulmonary Disease by Exercise and Nutrition

Submission date 23/08/2007	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 23/08/2007	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 06/05/2008	Condition category Respiratory	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
The effect of nutritional supplementation as adjunct to exercise training on resting and exercise-induced oxidative stress, muscle function and exercise capacity in severe Chronic Obstructive Pulmonary Disease patients

Acronym

ROXCEN

Study objectives

Daily ingestion of a nutritional supplement enriched with antioxidants during eight weeks pulmonary rehabilitation results in a decreased oxidative stress in rest and after exercise in Chronic Obstructive Pulmonary Disease (COPD) patients compared to an iso-caloric placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Ethical Commission of the METC of Maastricht on the 19th September 2007 (ref: NL17788.068.07/MEC 07-3-066).

Primary study design

Interventional

Study design

Double-blind placebo controlled parallel intervention study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic Obstructive Pulmonary Disease (COPD)

Interventions

Nutritional supplement enriched with antioxidants versus iso-caloric placebo.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Nutritional supplement

Primary outcome(s)

To assess the effect of daily ingestion of a nutritional supplement enriched with antioxidants during eight weeks pulmonary rehabilitation on resting and exercise-induced oxidative stress in COPD patients compared to an iso-caloric placebo. Oxidative stress will be measured by specific biomarkers in exhaled air, breath condensate, urine and venous blood, measured at the start of the rehabilitation and after eight weeks.

Key secondary outcome(s)

To examine the effects of daily ingestion of a nutritional supplement enriched with antioxidants during pulmonary rehabilitation on respiratory and skeletal muscle strength and exercise capacity in COPD patients, measured at the start of the rehabilitation and after eight weeks.

Completion date

01/07/2008

Eligibility

Key inclusion criteria

1. Diagnosis of COPD according to the American Thoracic Society (ATS) Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines (Forced Expiratory Volume in one second [FEV1] less than 60% predicted and FEV1/Forced Vital Capacity [FVC] less than 70% and less than 10% predicted improvement in FEV1 after b2-agonist inhalation
2. Both male and female, age-range from 40 to 75 years
3. No respiratory tract infection or exacerbation of the disease for at least four weeks before the study
4. Capable to provide informed consent
5. Presence of other chronic diseases is allowed in case the clinical status is stable for at least four weeks before the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Inability to perform the incremental cycle ergometer test
2. Chronic use of antioxidants or vitamin supplements
3. Investigator's uncertainty about the willingness or ability of the patient to comply with the protocol requirements
4. Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study
5. Specific allergy or intolerance

Date of first enrolment

01/10/2007

Date of final enrolment

01/07/2008

Locations

Countries of recruitment

Netherlands

Study participating centre
Research, Development and Education
Horn
Netherlands
6080 NM

Sponsor information

Organisation
Numico Research B.V. (The Netherlands)

ROR
<https://ror.org/00aj77a24>

Funder(s)

Funder type
Industry

Funder Name
Numico Research B.V. (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration