ISRCTN62421408 https://doi.org/10.1186/ISRCTN62421408

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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).

Study design
Double-blind placebo controlled parallel intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/10/2007

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

Age group
Adult

Sex
Both

Target number of participants
30

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)

Sponsor details
P.O.Box 7005
Wageningen
Netherlands
6700 CA

Sponsor type
Industry

Website
http://www.numico.com

ROR
https://ror.org/00aj77a24

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration