Reduction of oxidative stress in COPD by a combination of exercise and nutrition

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Daily ingestion of a nutritional supplement enriched with antioxidants during 8 weeks pulmonary rehabilitation results in a decreased oxidative stress in rest and after exercise in COPD patients compared to an iso-caloric placebo.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21716

Bron
NTR

Verkorte titel
ROXCEN

Aandoening

COPD, supplementation, antioxidants, rehabilitation

COPD, supplementatie, antioxidatnen, revalidatie

Ondersteuning

Primaire sponsor: AMWJ Schols, Prof
Director NUTRIM
University Maastricht
Postbus 616
6200 MD Maastricht
the Netherlands
Overige ondersteuning: NUMICO Research B.V.
P.O.Box 7005
6700 CA Wageningen
the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To asses the effect of daily ingestion of a nutritional supplement enriched with antioxidants during 8 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.

Toelichting onderzoek

Achtergrond van het onderzoek

Study to evaluate the effect of daily placebo-controlled nutritional supplementation enriched with antioxidants on the resting and exercise-induced oxidative stress in patients with COPD following a pulmonary rehabilitation.

Doel van het onderzoek

Daily ingestion of a nutritional supplement enriched with antioxidants during 8 weeks pulmonary rehabilitation results in a decreased oxidative stress in rest and after exercise in COPD patients compared to an iso-caloric placebo.

Onderzoeksproduct en/of interventie

Nutritional supplement enriched with antioxidants vs. iso-caloric placebo

Contactpersonen

Publiek

Research, Development and Education
Centre for Integrated Rehabilitation of Organ Failure (CIRO)
EPA Rutten
Hornerheide 1
Horn 6080NM
The Netherlands

Wetenschappelijk

Research, Development and Education
Centre for Integrated Rehabilitation of Organ Failure (CIRO)
EPA Rutten
Hornerheide 1
Horn 6080NM
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosis of COPD according to the American Thoracic Society (ATS) GOLD guidelines (FEV1 < 60% predicted and FEV1/FVC < 70% and < 10% predicted improvement in FEV1 after b2-agonist inhalation (14, 15));
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 4 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 4 weeks before the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2007
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL991
NTR-old	NTR1020
Ander register	:

Register	ID
ISRCTN	ISRCTN62421408

Resultaten