ISRCTN86049077 https://doi.org/10.1186/ISRCTN86049077

Chronic obstructive pulmonary disease (COPD) as syndrome of accelerated aging

Submission date 15/03/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/05/2010	**Overall study status** Completed	
Last Edited 18/05/2010	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Erica Rutten

Contact details
Centre for Integrated Rehabilitation of Organ Failure (CIRO)
P.O. Box 4080
Horn
Netherlands
6080 AB
ericarutten@ciro-horn.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3.2.09.049

Study information

Scientific Title
Systemic manifestation and co-morbidity in chronic obstructive pulmonary disease (COPD) are associated with circulating markers of aging: a cross-sectional observational study with a longitudinal follow-up for two years

Acronym
AGOPD

Study objectives
We hypothesise that accelerated aging is a key pathophysiological mechanism of chronic obstructive pulmonary disease (COPD), and that aging markers are related to important domains of the disease, particularly to the systemic phenotype of COPD and the clinically manifested co-morbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Maastricht Medical Etical Commission, pending as of 16/03/2010

Study design
Cross-sectional observational study with a longitudinal follow-up

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
At baseline and 2 years later, the participants will be invited for two test days; one day at the Center of Expertise for Chronic Organ Failure (CIRO), Horn, and one day at the Maastricht University Medical Center (MUMC).

For COPD patients, the test days will be planned before the start of the rehabilitation. The first day and after overnight fast, venous blood of about 30 ml venous blood in total will be collected, an amount which is not of clinical relevance, but the venepuncture can cause a blue spot. The electrocardiography and the pulse wave velocity will also be performed in the fasted state.

During this procedure, the arm will be occluded for 5 minutes. This may give a tingling feeling, but this feeling disappears when the occlusion is removed. Dual x-ray absorptiometry scan will be performed after emptying the bladder and a lung function measurement will take place after consuming breakfast. On the second day at the MUMC, all subjects will be invited for a high resolution computed tomography (HRCT) scan of the thorax.

During the follow-up of 2 years, medical status of the participants will be followed by a telephone contact every three months. For the COPD patients, lung function measurement and dual energy x-ray absorptiometry (DEXA) scan will be performed during the assessment of the rehabilitation at baseline. These tests do not have to be repeated. In a subgroup of 25 patients with the emphysema like phenotype, 25 patients with the non-emphysema like phenotype and 50 smoking healthy controls, circulating concentration of hepatokines and deoxyribonucleic acid (DNA) repair mechanism will be detected in a second venous blood sample during the second test day.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
All analysed at baseline:
1. Markers of aging
2. Objective diagnosed co-morbidity
3. Circulating hepatokines

Secondary outcome measures
All analysed at baseline:
1. Markers of systemic inflammation and oxidative stress
2. Classic characterisation of COPD

Overall study start date
01/10/2010

Completion date
01/10/2014

Eligibility

Key inclusion criteria
COPD patients:
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 80% predicted and FEV1/forced vital capacity [FVC] less than 70% and less than 10% predicted improvement in FEV1 after Ò2-agonist inhalation
2. Both male and female, aged from 50 to 75 years
3. No respiratory tract infection or exacerbation of the disease for less than 4 weeks before the study
4. Capable of providing informed consent

Healthy subjects:
1. Healthy subjects as judged by a physician
2. Without diagnosed COPD or any other described co-morbidity/chronic disease
3. Both male and female, aged from 50 to 75 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600

Key exclusion criteria
COPD patients:
1. Any kind of carcinogenic pathology less than 5 years before study participation
2. Participation in any other studies involving investigational or marketed products concomitantly or less than 4 weeks prior to entry into the study

Healthy subjects:
1. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements
2. Participation in any other study involving investigational or marketed products concomitantly or within two weeks prior to entry into the study

Date of first enrolment
01/10/2010

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Centre for Integrated Rehabilitation of Organ Failure (CIRO)
Horn
Netherlands
6080 AB

Sponsor information

Organisation
Dutch Asthma Foundation (Netherlands)

Sponsor details
P.O.Box 5
Leusden
Netherlands
3830 AA

Sponsor type
Research organisation

Website
http://www.astmafonds.nl

ROR
https://ror.org/00ddgbf74

Funder(s)

Funder type
Research organisation

Funder Name
Dutch Asthma Foundation (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