An Exploratory Observational, Single-Centre Study in Patients with Disabling Chronic Obstructive Pulmonary Disease to Identify Biomarkers for *Systemic Disease*, Co-Morbidities, Increased Health Care Costs and Poor Prognosis. (CIROCO).

Published: 04-07-2007
Last updated: 11-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON39306

Source
ToetsingOnline

Brief title
CIROCO study

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic bronchitis, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Astra Zeneca
Source(s) of monetary or material Support: Door AstraZeneca (de afdeling Research and Development in Charnwood;UK)

Intervention

Keyword: biomarkers, COPD, Health care costs, Long-term

Outcome measures

Primary outcome

Biomarkers in the blood, a range of approximately 20 parameters, there will be a search for predicting factors on exacerbation frequency and mortality on the long term and for the effect of the lung rehabilitation on these biomarkers on the short term. The number of exacerbations will be recorded.

Secondary outcome

Investigating the number of exacerbations, hospitalisations, progression of COPD, mortality, health care use, quality of life over a long term follow-up period.

Searching for correlations between biomarkers in blood and bonde density, muscle quality and peripheral vasculature quality. Studying the effects of rehabilitation program on muscle quality.

Study description

Background summary

COPD (Chronic Obstrcutive Pulmonary Disease) is a smoking related disease with

an increasing incidence and a great burden of illness.

Besides the lungs and airways other organs are affected, such as bloodvessels, muscles and bones, in line with a systemische inflammation, existing besides the locale inflammation.

At this moment there are no good predicting factors for the course of COPD.

Part of the COPD patients shows a slow gradual decline of among others lungfunction, but a larger proportion of the patients present themselfes with a rapid decline and with frequent exacerbations, necessitating hospitalisations.

The costs of severe COPD are not well-investigated yet and will be studied in this investigation and compared to those in mild COPD and in healthy ccontrol subjects.

Study objective

The main objective of the current study is to search for biomarkers, which will be investigated with their predictive value with respect to the course of COPD in lungfunction, exacerbations, health care use and mortality. The effects of the rehabilitation program on the biomarkers will also be investigated.

Three groups of persons will be followed (after an extended initial investigation) after inclusion for 5 years: een group of approximately 220 patients with severe COPD (who are already participating in a 8 - 14 weeks lung rehabilitaion program), a group of 40 patients with mild COPD and a group of 50 healthy control subjects.

Study design

Observational study, every three months in a telephone call lasting approximately 30 minutes they will be asked extensively after their health, use of medicines and health care use.

At the start of the study extensive tests are perforemd, among others for lung function, bone density, the condition of peripheral vasculature status and th edistance which can be walked in 6 minutes. Those test will be repeated at the end of the 2 years follow-up.

The patients with mild COPD and the healthy control subjects wil be subjected to a part of the assessments in the severe COPD patients.

After 2 years fo follow up, only survival status will be evaluated yearly for another 3 years.

Study burden and risks

The burden for severe COPD patients is the series of extra tests, besides those they already were exposed to during thier lung rehabilitation, an extra investigation at the end of 2 years follow-up and conducting telephone calls every three months. A bone densitometry will be made, peripheral blood vasculature will be investigated and (optionally) investigations are done on muscle.

For mild COPD patients and the healthy control subjects the burden consists of a small extra number of tests besides those already performed when the patients participated in the BOLD study in the previous period and the telephone calls.

In a subgroup of 20 patients with severe COPD and 20 healthy control subjects an additional muscle biopsy will be obtained.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Severe COPD: 1: referred to the CIRO in Horn for a lung rehabiliation program 2: agreeing to participate and signed "informed consent", 3: age 40 - 80 year, 4: lungfunction (post-bronchodilator FEV1) below 80% of predicted, 5: ratio FEV1 / FVC (post-bronchodilator) below 0.70, 6: current or ex-smoker with at least 10 pack-years
Healthy control subjects: 1: agreeing yto participate and signed "informed consent" , 2; age 40 - 80 years, 3: healthy, 4: lungfunction (post-bronchodilator FEV1) above 85% of predicted, 5: Ratio FEV1 / FVC (post bronchodilator) above 85% of predicted, 6: non-smoker or ex-smoker with less than 10 pack-years.
Mild COPD: 1: agreeing to particpate and signed "informed consent" , 2: COPD diagnosis confirmed in the BOLD project.

Exclusion criteria

All participants: history of asthma, other lung disease, severe cardiac disease, rheumatoid arthritis, bone disease, other concomitant disease, malignancy, pregnancy, physical handicap making walking impossible, alcohol or drug abuse, recent blood donation.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-11-2007
Enrollment:	310

Type:	Actual

Ethics review

Approved WMO Date:	04-07-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-07-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-04-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-09-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-01-2014
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL17373.040.07