General Risk factors And iNflammatory Determinants in younger PAtients with copd: the GRANDPA study

Published: 04-10-2019
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To compare young and old COPD immunologically, physiologically, risk factors, patient behaviour and quality of life.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational non invasive

Summary

ID

NL-OMON52605

Source
ToetsingOnline

Brief title
GRANDPA study

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
COPD, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Ziekenhuis
Source(s) of monetary or material Support: Bedrijven,Boehringer Ingelheim,Chiesi Farmaceutici,TEVA Pharma

Intervention

Keyword: COPD, inflammation, obstructive lung disease, treatable traits

Outcome measures

Primary outcome

1a. Cross sectional design To compare the differences in number of inflammatory cells (eosinophils, neutrophils, ILC1 cells, ILC2 cells and cytokines) in blood and sputum in COPD patients and controls during stable disease.

1b. Longitudinal study design To compare the differences in number of inflammatory cells (leucocyte differentiation, ILC1 cells, ILC2 cells and cytokines) in blood during stable disease and exacerbation in COPD patients.

Secondary outcome

2a. Cross sectional study design To measure physiological factors (lung function, activity level) and relate them to inflammatory profile.

2b. Cross sectional study design To study the effect of aging on inflammation, physiology, psychology, quality of life and co- morbidities in COPD.

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is a chronic lung disease characterized by persistent symptoms of inflammation and non-reversible airway obstruction. It is associated with small airways disease and/or parenchymal destruction (emphysema). The high mortality rate makes it the fourth leading cause of death. The global prevalence of COPD is 11.7% (1). Inhalation of cigarette smoke plays an important part in inducing COPD. The disease presents mostly after the age of 40, due to the cumulative effects of smoking. Around 25% of the COPD patients is younger than 60 and 36% is younger than 65 years

(2). COPD patients under the age of 60 are seen as young patients. The impact of COPD on daily life and work participation is high, especially in young patients. Furthermore, little is known about the phenotype of young COPD patients.
This resulted in the following research questions:
1. What is the difference in number of inflammatory cells (eosinophils, neutrophils, ILC1 cells, ILC2 cells and cytokines) in blood and sputum of different subgroups of COPD (young and old) during stable disease as well as in a period of exacerbation?
2. Can we relate physiological factors (lung function and activity level) to the inflammatory profile?
3. What*s the effect of aging on inflammation, physiology, quality of life and co-morbidities in COPD?

Study objective

To compare young and old COPD immunologically, physiologically, risk factors, patient behaviour and quality of life.

Study design

A part of the study is a cross-sectional study in which we will compare patients with COPD. Healthy controls serve as comparison per age group.
The primary outcome is difference in number of ILC2 cells in blood between the COPD patients and controls. Another part of the study is a longitudinal design in which we compare ILC1 and ILC2 in stable disease and during exacerbation in COPD patients.
Sputum, blood, physiological and clinical data will be collected during stable disease and during exacerbation. The number of cells, morphology, and activation status will be studied in various immune cells.

Study burden and risks

No personal benefit from participation in the GRANDPA study is expected. The study comprises two scheduled visits. The first visit is already standard practice. Most procedures are non-invasive (e.g. spirometry, use of move-monitor, symptom score and quality of life assessment, cardiography). Two procedures are more invasive and may be cause discomfort for the patient. First, one blood sample will be taken (100 ml) and second, sputum induction will be performed. This is regarded as a safe procedure and may cause temporarily dyspnea and cough. The results from this study could be beneficial for the patient population.

Contacts

Public
Franciscus Ziekenhuis

Kleiweg 500
Rotterdam 3045PM
NL
Scientific
Franciscus Ziekenhuis

Kleiweg 500
Rotterdam 3045PM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
Inclusion criteria subjects with COPD
• Age 40+ years
• COPD gold II-IV; FEV 1< 80%
• Active or ex-smoker > 10 pack years
• Willing and able to comply with the study protocol
• COPD diagnosis is based on presence of airflow obstruction (post-bronchodilator spirometry FEV1/ FVC with z-score < -1.64)

Exclusion criteria

• Not full comprehensive in the Dutch language.
• A liaison with the coordinating or principal investigator, which could likely influence the decision to participate in this study voluntarily (in concordance with the WMO - article 5)
• Other diseases which could influence pulmonary function and/or the immune system such as:
o A possible infection of the upper- or lower respiratory tract 6 weeks prior to the collection of materials;
o Active malignancy
o Lung cancer diagnosis (also in the past)
o Asthma as the predominant disease according to the investigator's opinion, a past history of asthma is allowed.
o Current pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-2019
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	04-10-2019
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-04-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26068
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70290.100.19
Other	NL8286 (Netherlands Trial Registry)
OMON	NL-OMON26068