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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26068

Source
Nationaal Trial Register

Brief title
GRANDPA

Health condition

COPD

Sponsors and support

Primary sponsor: Franciscus Gasthuis en Vlietland
Source(s) of monetary or material Support: Boehringer Ingelheim:Chiesi

Intervention

Outcome measures

Primary outcome

Immunology: ILC1 cells, ILC2 cells, ratio ILC1/ILC2, cytokines, Th-subset profiles.

Secondary outcome

• Pathophysiology: TLC, FRC, FVC, sVC, iVC, FEV1 pre/post, RV, CO-diffusion, metronome paced tachypnea (dynamic hyperinflation with reversibility), MIP (maximal inspiratory pressure), iOS (impulse oscillometry). Haematology parameters, lipid profile, BMI and FeNO
• Behavior: Move-monitor, quality of life, coping. (Questionnaires: CAT, MRC, CCQ, EQ-5D-5L, TASMAN, NL-PIH.)
• Inflammatory parameters: in blood CRP, TRAIL, IP-10, lipid profile, eosinophils and neutrophils (both in sputum and in blood).
• History of risk factors: host factors (genetic factor alfa 1 anti trypsin deficiency, congenital), tobacco smoke, smoke from home cooking and heating fuels, occupational dusts, vapours, fumes, gases and other chemicals. Living conditions (living nearby harbour or highway). Birthweight, respiratory infections as a child. Exacerbation rate.

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. Describe the relationship between physiological factors (lung function and activity level) and the inflammatory profile.
3. What’s the effect of aging on inflammation, physiology, quality of life and co-morbidities in COPD?

Study objective

1. Young COPD patients have an inflammatory profile which is different from old COPD patients characterized by more plasticity of ILC2 to ILC1 (cross-sectional study design).
2. To compare the differences in number of inflammatory cells (leucocyte differentiation, ILC1 cells, ILC2 cells and cytokines) in blood during stable disease and exacerbation (longitudinal study design).

Study design

2 visits (pulmonary function test, blood samples) and 1 exacerbation visit

Intervention

Blood samples, comorbidity, questionnaires (CCQ, CAT, EQ-5D-3L, PAM, TASMAN, PIH-NL, MRC), Pulmonary function test, movemonitor, sputum collection.

Contacts

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Eligibility criteria

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 between 40-80 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)

Inclusion criteria subjects without COPD
• Age between 40-80 years
• Willing and able to comply with the study protocol
• Active or ex-smoker > 10 pack years
• No COPD diagnosis, based on absence of airflow obstruction (post-bronchodilator spirometry FEV1/ FVC with z-score < -1.64)

• FEV1 > 80%
• Diffusing capacity > 70%

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

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 (History or current) asthma diagnosis
o Current pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2020
Enrollment:	90
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	15-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52605
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8286
CCMO	NL70290.100.19
OMON	NL-OMON52605

Study results