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

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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...

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON26068

**Bron**
NTR

**Verkorte titel**
GRANDPA

**Aandoening**

COPD

### Ondersteuning

**Primaire sponsor:** Franciscus Gasthuis en Vlietland
**Overige ondersteuning:** Boehringer Ingelheim:Chiesi

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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?

### Doel van het onderzoek

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).

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

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

# Contactpersonen

## Publiek

Franciscus Gasthuis en Vlietland
Cathelijne van Zelst

06-18975719

## Wetenschappelijk

Franciscus Gasthuis en Vlietland
Cathelijne van Zelst

06-18975719

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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%

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Niet-gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 15-01-2020 |
| Aantal proefpersonen: | 90 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Ja

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 15-01-2020 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52605
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

# Resultaten