Autoimmunity in Chronic Obstructive Pulmonary Disease.

No registrations found.

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

Summary

ID

NL-OMON26251

Source
NTR

Health condition

Chronic Obstructive Pulmonary Disease, COPD, Autoimmunity, lung, smoking, cytotoxicity, antibodies

Chronische Obstructieve Bronchitis en Longemfyseem, autoimmuniteit, long, roken, cytotoxiciteit, antilichamen

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Hanzeplein 1
Postbus 30.001
9700 RB Groningen
The Netherlands
Source(s) of monetary or material Support: Dutch Asthma Foundation

Intervention

Outcome measures

Primary outcome

1. The degree of autoantibody-mediated cytotoxicity of sera of COPD patients when compared to non-COPD patients, expressed as a fraction of cells that have died during incubation;

2. The cell types (primary bronchial epithelial cells, primary airway smooth muscle cells, primary lung fibroblasts) and cell lines (an alveolar epithelial cell line and a lung fibroblast cell line) that are primarily affected by autoantibodies as found in serum of COPD patients and healthy controls;

3. The contribution of complement, different effector cells, and antibody-free serum to the level (as outlined in the previous paragraphs) and specificity of cytotoxicity (which cells and cell lines are affected). The impact of different effector cells and antibody-free serum.

Secondary outcome

1. Effects of age, aspects of smoking history, clinical and immunological parameters on cytotoxicity;

2. Insight into the components which play a role in lung remodelling and destruction. We expect that results will lead to more attention for COPD and more focus on relevant targets in drug development programs;

3. A better understanding of the mechanisms underlying the pathological changes in lungs of patients with COPD, and identification of characteristics of patients which may benefit from anti-autoimmune therapy. This is necessary to be able to develop more targeted drug development programs and to develop efficient therapies;

4. Due to the similarities of COPD to other autoimmune disease (outlined above), opportunities for improved treatment and medication may in part be based on regimes used in other autoimmune diseases.

Study description

Background summary

N/A

Study objective

Chronic Obstructive Pulmonary Disease is a disease of the lungs for which adequate treatment lacks. We hypothesize that there is a role for autoimmunity in this disease.

Study design

N/A

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria for COPD patients:

1. Clinical diagnose of COPD;

2. No allergies;

3. Post-bronchodilator FEV1 < 80% predicted, and postbronchodilator FEV1/FVC < 70% (in accordance with the GOLD stages mentioned above);

4. Age > 40;

5. Current or ex-smokers > 10 pack years;

6. Ex-smokers have to have quitted smoking for at least one year;

7. No other major current health problems;

8. Written informed consent.

Healthy controls:

1. No signs of pulmonary disease;

2. No allergies;

3. No other major current health problems;

4. FEV1 > 90 % predicted and FEV1/FVC > 70%;

5. Age > 40;

6. Never smokers, i.e. no cigarettes last year, and < 5 pack years, or current smokers > 10 pack years; or ex- smokers for > 1 year and > 10 pack years;

7. Written informed consent.

Exclusion criteria

1. Addiction to alcohol or drugs;

2. COPD exacerbation in the 6 weeks preceding the study;

3. Immunosuppressive therapy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2010
Enrollment:	120

Type:	Anticipated

Ethics review

Positive opinion Date:	25-03-2010
Application type:	First submission

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
NTR-new	NL2135
NTR-old	NTR2259
Other	Dutch Asthma Foundation : 3.2.08.021
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A