COPD: Transition of systemic inflammation into multiorgan pathology (study 3).

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To investigate in COPD whether: 1. systemic inflammation and multi-organ disease is more pronounced in more severe COPD2. quadriceps oxidative capacity and fiber type I proportion is reduced, and whether age, sex, smoking, physical activity, GOLD...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Congenital respiratory tract disorders
Study type	Observational invasive

Summary

ID

NL-OMON32013

Source
ToetsingOnline

Brief title
Multiorgan pathology in COPD

Condition

- Congenital respiratory tract disorders

Synonym
chronic obstructive bronchitis (COPD), emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Altana Pharma,GlaxoSmithKline,Numico,Nycomed,TI Pharma

Intervention

Keyword: COPD, inflammation, smoking, susceptibility

Outcome measures

Primary outcome

1. Smoking history and behaviour, diet and physical activity level assessed by questionnaire

2. Extensive lung function and CT scanning of the lung

3. Candidate genes for muscle dysfunction and CVD risk

4. Body composition

5. Systemic inflammation

6. Risk factors of metabolic syndrome

7. AGES

8. 6 minute walking distance

9. handgrip strength

10. physical activity level by questionnaire

11. Muscle oxidative phenotype, fibre cross-sectional area and molecular signatures obtained in vastus lateralis muscle biopsies before and after incremental cycly ergometry

12. Skeletal muscle function by isokinetic dynamometry

13. Physical activity level and pattern by accelerometry

14. Glucose tolerance test

Secondary outcome

n.a.

Study description

Background summary

There is increasing evidence in the literature that COPD should not be considered as a localised pulmonary disorder but as a systemic disease involving pathology in several extra pulmonary tissues. Well characterized systemic features are a chronic low grade systemic inflammation, altered body composition and a skeletal muscle fibre type shift. There are indications that an absolute or relative increase of fat mass puts COPD patients at increased risk for cardiovascular pathology while muscle atrophy is associated with a high prevalence of osteoporosis and with impaired physical function. The origin of systemic inflammation is poorly understood. Both endogenous and exogenous risk factors contribute to systemic inflammation and extra-pulmonary manifestations of COPD. Endogenous risk factors such as gene polymorphisms, ageing and neurohormonal activation will be important but have not been investigated so far at the level of extra- pulmonary manifestations.

Study objective

To investigate in COPD whether:
1. systemic inflammation and multi-organ disease is more pronounced in more severe COPD
2. quadriceps oxidative capacity and fiber type I proportion is reduced, and whether age, sex, smoking, physical activity, GOLD stage, and co-morbidity contribute to this
3. systemic and muscle inflammatory profile is associated with muscle oxidative phenotype and insulin sensitivity
4. the emphysema phenotype affects the level of systemic inflammation and muscular inflammatory status
5. cardiovascular risk factors are related to body composition, muscle oxidative status and lung function
6. skeletal muscle weakness affects exercise capacity and health status also in mild to moderate COPD.

Study design

Cross-sectional study. Healthy smoking subjects and COPD patients will undergo extensive clinical, metabolic and inflammatory assessment at the university clinics in Groningen, Maastricht and CIRO Horn.

Study burden and risks

• Totally 17 hours will be spend in the hospital during 3 visits
• Metacholine provocation and sputum induction may cause temporary

bronchoconstriction in subjects with increased hyperresponsiveness.
• CT-scanning of the lung is associated with a radiation burden of 0.8-1.6 mSv (dependent of body weight)
• 32 ml peripheral blood (v. cubiti)
• Muscle biopsy may be associated with temporary pain and haematoma.

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

• Age 40-75 years
• Age, pack years, FEV1/FVC and FEV1% predicted must fit in one of 2 groups of table 4.3
• Physically and mentally able to undergo the total study protocol
• Written informed consent

Exclusion criteria

• Participation in another study
• asthma
• Alpha-1-antitrypsin deficiency
• Selected within the red made gradation of the 1-3 co-morbidity list in the ACE-27
• Active pulmonary infection like tuberculosis, pneumonia, flue, tracheobronchitis
• Active extra-pulmonary infection like hepatitis A-C, cystitis, gastro-enteritis etc
• Pulmonary diseases like sarcoidosis, IPF, silicosis, hypersensitivity pneumonitis
• Life threatening diseases like carcinoma, AIDS (including HIV+), acute leukaemia etc
• Medication that may affect the results of the study: NSAID*s, immunosuppressive agents like prednisolon, metotrexate, azathioprine, sintrom tablets

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL23475.042.08
Other	Wordt nog gedaan