Platelet reactivity and formation of platelet-monocyte complexes in patients with chronic obstructive pulmonary disease (COPD)

Published: 28-07-2015
Last updated: 19-04-2024

Objective: To compare platelet reactivity and formation of platelet-monocyte complexes between patients with COPD and age-matched controls and to relate this to systemic inflammation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON42526

Source
ToetsingOnline

Brief title
COPD reactivity

Condition

- Coronary artery disorders
- Bronchial disorders (excl neoplasms)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
COPD chronic obstructive pulmonary disease

Research involving
Human

Sponsors and support

Primary sponsor: Longziekten
Source(s) of monetary or material Support: Longfonds

Intervention

Keyword: Cardiovascular risk, COPD, Platelets, reactivity

Outcome measures

Primary outcome

Parameters are platelet reactivity (platelet expression of the platelet activation marker CD62P (P-selectin) and activated fibrinogen receptor (αIIbβ3) upon stimulation with different platelet agonists), platelet-monocyte complexes, soluble markers of platelet activation and inflammatory cytokines and the relation of platelet activation to GOLD classification, exacerbation rate, smoking and lung function.

Secondary outcome

See primairy outcomes.

Study description

Background summary

Rationale: Patients with chronic obstructive pulmonary disease (COPD) are at increased risk of cardiovascular disease(CVD). Exacerbations increase this risk further and prevalence of CVD increases with COPD severity. Patients with COPD have increased baseline levels of systemic inflammation and systemic inflammation this is thought to play an important role in platelet activation. Platelet activation leads to platelet aggregation and formation of platelet-monocyte complexes an early process in thrombosis. So far, no studies have focused on platelet reactivity, a marker of platelet responsiveness and functionality, and their relation to inflammatory cytokines in patients with COPD. We hypothesise that platelet activation in COPD is caused by low grade systemic inflammation and that platelets are hyper responsive upon stimulation,

a possible risk factor for CVD.

Study objective

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Study design

Observational cohort study.

Study burden and risks

Participation in this study involves a maximum of one extra venipuncture during a regular visit to the outpatient clinic. Blood drawn before a diagnostic maximum exercise cycle test requires no extra venipuncture. Amount of blood drawn is 19.5 mL. The burden and risks are minimal and venapuncture is generally considered safe.

Contacts

Public
Selecteer

Geert Grooteplein-Zuid 10
Nijmegen 6500HB
NL
Scientific
Selecteer

Geert Grooteplein-Zuid 10
Nijmegen 6500HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study the COPD subjects must meet all of the following criteria:
• >40 years
• Bronchus obstruction detected by spirometry: FEV1/FVC ratio < 70% and postbronchodilatory FEV1<80% (COPD Gold II-IV) and clinical diagnosis confirmed by a pulmonologist.
• >=10 pack years of smoking

Exclusion criteria

• Use of aspirin or other platelet function inhibitors
• Asthma
• Chronic inflammatory diseases, such as rheumatoid arthritis, psoriasis, inflammatory bowel diseases , systemic lupus erythematous (SLE)
• Malignancies
Regarding the control subjects the inclusion criteria described above do not apply, however the exclusion criteria do apply.

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-10-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	28-07-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL53202.091.15