Platelet activation and responsiveness in patients with acute exacerbations of chronic obstructive pulmonary disease (AE-COPD)

Published: 02-11-2016
Last updated: 15-04-2024

To determine: 1) baseline platelet activation, 2) platelet responses to stimulation with different platelet agonists, 3) formation of platelet-monocyte complexes), 4) effects on plasmatic coagulation, 5) soluble markers of platelet activation and...

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

Summary

ID

NL-OMON45449

Source
ToetsingOnline

Brief title
AE-COPD reactivity

Condition

- Coronary artery disorders
- Bronchial disorders (excl neoplasms)

Synonym
COPD - obstructive lung disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: PhD student wordt betaald uit een subsidie van het longfonds

Intervention

Keyword: cardiovascular risk, COPD, platelet activation

Outcome measures

Primary outcome

1/2) Platelet activation: platelet expression of the platelet activation marker CD62P (P-selectin) and binding of fibrinogen to the activated fibrinogen receptor (*IIb*3) at baseline and upon stimulation with different platelet agonists. 3) Platelet-monocyte complexes. 4) Tissue factor (TF) triggered thrombin generation. 5) Soluble (plasma) markers of platelet activation and inflammatory cytokines.

Secondary outcome

Please see the section primary study parameters

Study description

Background summary

Chronic obstructive pulmonary disease (COPD) is known for development of severe cardiovascular co-morbidities. Systemic inflammation is thought to play a role in development of cardiovascular disease. During acute exacerbations of COPD (AE-COPD), systemic inflammation increases considerably. Systemic inflammation drives activation of immune cells, including platelets. Upon activation, P-selectin is released by platelets and bound to the platelet surface, enabling formation of platelet-monocyte complexes (PMCs), an early process in atherothrombosis. Fibrinogen release from platelets effectuates clot formation, platelet aggregation and adhesion of platelets to the vascular endothelial surface. In COPD, platelet function in AE-COPD is scarcely studied. This study

aims to address this gap by investigating platelet function and coagulation in patients with AE-COPD and after convalescence.

Study objective

To determine: 1) baseline platelet activation, 2) platelet responses to stimulation with different platelet agonists, 3) formation of platelet-monocyte complexes), 4) effects on plasmatic coagulation, 5) soluble markers of platelet activation and inflammation, in patients with AE-COPD and after convalescence.

Study design

This study is designed as an exploratory observational cohort study involving adult patients with an acute exacerbation of COPD by the department of respiratory diseases in Radboudumc and UCCZ Dekkerswald.

Study burden and risks

Participation in this study involves one venipuncture during an AE-COPD and one venipuncture during a regular follow-up visit to the outpatient clinic. The total amount of blood drawn for study purposes is 24mL. The burden is limited and risks are minimal, as venipuncture is generally considered save.

Contacts

Public
Academisch Medisch Centrum

Geert Grooteplein-Zuid 22
Nijmegen 6525 GA
NL
Scientific
Academisch Medisch Centrum

Geert Grooteplein-Zuid 22
Nijmegen 6525 GA
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
* Spirometry confirmed diagnosis of COPD (i.e. post-bronchodilator FEV1/FVC < Lower limit of normal (LLN)).
* *10 pack years of smoking

Exclusion criteria

* Use of anti-coagulation, aspirin or platelet function inhibitors, with the exception of cyclooxygenase inhibitors (e.g, carbasalate calcium, acetylsalicylic acid)
* Asthma
* Chronic inflammatory diseases, such as rheumatoid arthritis, psoriasis, inflammatory bowel diseases , systemic lupus erythematous (SLE)
* Malignancies

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-01-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	02-11-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-03-2017
Application type:	Amendment
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	NL59277.091.16