Impact of airflow limitation in chronic heart failure

Published: 16-05-2012
Last updated: 26-04-2024

The primary objective is to establish the point prevalence of Airflow Limitation (AL) compatible with COPD in patients with congestive heart failure (CHF) seen in a single centre in the Netherlands.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON37787

Source
ToetsingOnline

Brief title
ALICE-HF

Condition

- Heart failures
- Respiratory disorders NEC

Synonym
airflow limitation, heartfailure

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: GlaxoSmithKline,GSK

Intervention

Keyword: Airflow limitation, heart failure

Outcome measures

Primary outcome

Airflow limitation (AL), defined as FEV1/FVC < 0.70 (post bronchodilator)

Secondary outcome

* Severity of AL, as defined by GOLD stages;

* Restrictive AL, defined by FEV1/FVC *0.70 and a predicted FVC <80% (post bronchodilator)

* AL as defined by FEV1 below the lower limit of normal (LLN), as measured by standardized spirometry equipment;

* Diffusion capacity for carbon monoxide, using the single breath method.

* Presence of past history of airflow limitation or COPD;

* Health status questionnaire scores (mMRC dyspnoea score; Kansas City Cardiomyopathy Questionnaire, SF-12, and COPD Assessment Test (CAT));

* Healthcare utilisation: Number of emergency room visits and hospital admissions in previous 12 months.

Study description

Background summary

Dyspnoea is a common symptom, particularly in elderly patients, but it is not specific for a single disease. The most common diseases causing dyspnoea are heart failure (HF) and COPD. Usually, the clinical focus is posed either on heart failure or COPD, but due to the common risk factors, i.e. age and

smoking, many patients are suffering from both diseases. However, the co-existence of the two diseases is often missed or treatment commented without proper diagnostics, which is why patients are often not optimally treated. Therefore, we aim to overcome this clinically important shortcoming by investigating consecutive patients diagnosed with and treated for heart failure with respect to the prevalence of airflow limitation and the clinical consequences thereof. Moreover, we aim to identify patients at risk for airflow limitation to significantly improve identification of these patients and, as a consequence, to improve care

Study objective

The primary objective is to establish the point prevalence of Airflow Limitation (AL) compatible with COPD in patients with congestive heart failure (CHF) seen in a single centre in the Netherlands.

Study design

cross-sectional, observational cohort study.

Study burden and risks

This is a mere observational study without any intervention. The information gathering will be based on lung function testing and short questionnaires, which is the main burden for the patients. Moreover, blood samples will be taken. Lung function testing and blood sampling will be performed by trained study personnel. The length of the questionnaires will be kept to a minimum. Quantitative data on patient*s characteristics will be largely taken from the already existing patient*s charts. Thus, there are no additional examinations necessary due to the study.
Overall, there is no major risk for individual patients in participating in this study. The potential benefit is related to the possible detection of unrecognised limitation in lung function, which may be then therapeutically addressed. This may help to reduce the burden of the patients related to dyspnoea

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

documented HeartFailure based on left ventricular dysfunction (irrespective of ejection fraction) (following current ESC guidelines)
age patients 50 years or older

Exclusion criteria

Patients for whom spiromerty is contra indicated
patients with recent surgery, myocardial infarction or cardiac decompensation, lower respiratory tract infection or stroke

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):	22-06-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	16-05-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL39223.068.12