Systematic development and validation of an exacerbation risk index for COPD patients in general practice: tailoring treatment to an individual*s needs

Published: 17-04-2008
Last updated: 07-05-2024

The development of a practical COPD disease severity index developed and validated in primary care settings and thus ready-for-use in primary care after completion of the proposed project.

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

Summary

ID

NL-OMON32202

Source
ToetsingOnline

Brief title
ICE COLD ERIC

Condition

- Other condition
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
chronic bronchitis, lung emphysema

Health condition

Experts currently see COPD as a systemic illness, not just as a pulmonary illness

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Nederlands Astmafonds

Intervention

Keyword: cohort study, COPD, cross validation, prognosis

Outcome measures

Primary outcome

Exacerbations and health-related quality of life

Secondary outcome

not applicable

Study description

Background summary

COPD is a systemic illness; morbidity and mortality due to this disease are on the increase, and it has great impact on patients* lives. Most COPD patients are managed by general practitioners (GP). GPs base their initial assessment of patients* disease severity mainly on lung function and the presence of airway symptoms, and then advise on adequate treatment. However, FEV1 and clinical symptoms correlate poorly with exacerbation frequency and/or health-related quality of life. Preventive cardiology embraced risk index-guided treatment successfully. Now, the European Respiratory Society (ERS) and American Thoracic Society (ATS) call for a COPD disease severity index that better represents the clinical manifestations of COPD.

Study objective

The development of a practical COPD disease severity index developed and validated in primary care settings and thus ready-for-use in primary care after completion of the proposed project.

Study design

We will conduct three linked prospective cohort studies with COPD patients (GOLD stages 2-4) from GPs in Switzerland, the Netherlands and, at a later stage, Canada. We will perform an extensive baseline assessment including detailed patient history, lung function, measurement of exercise capacity and blood sampling. During the follow-up of at least two years, we update the patients* profile by registering health status, exacerbations and health-related quality of life. Using multivariable regression analysis we will identify the best combination of variables predicting the course of health-related quality of life.

Study burden and risks

At baseline: single visit to nearby general practice for venepuncture (once, 40ml) and lung function test (before and after bronchodilation using a inhaled beta-2 adrenergic drug), questionnaires, two short exercise tests,
Follow-up: annually one 30-minute telephone interview (2 times, 5 times if further funding is acquired).

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients *40 years of age with COPD in GOLD stage II to IV (postbronchodilator FEV1/FVC*0.70, postbronchodilator FEV1*80% predicted are eligible if in- or outpatient treatment of their last exacerbation ended *4 weeks ago. If patients had an exacerbation in the previous 4 weeks, (s)he can be invited when free of exacerbations for at least 4 weeks. We will include any patient who is able to complete the baseline assessment.

Exclusion criteria

We will exclude patients who received mechanical ventilation in the previous 12 months because of their extremely poor prognosis and patients with co-morbidities associated with a life expectancy of *12 months. We will also exclude patients diagnosed with dementia, psychosis or other psychiatric illness that invalidate assessment of patient-reported parameters (health-related quality of life, physical activity, dyspnea etc). Finally, we will exclude patients if the baseline assessment including the questionnaires cannot be completed due to language difficulties.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2008

Enrollment:	220
Type:	Actual

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL22118.018.08