A decision model for the management of acute exacerbation chronic obstructive pulmonary disease in the emergency department: flowchart for treatment allocation.

Published: 12-10-2015
Last updated: 19-04-2024

The primary objective is to validate a previously established prognostic instrument in the form of an algorithm (flowchart) in patients that present with AECOPD to the department of emergency medicine for classifying for out- or inpatient treatment...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON44069

Source
ToetsingOnline

Brief title
AEC-F Trial: Acute Exacerbation COPD Flowchart

Condition

- Respiratory disorders NEC

Synonym
Acute Exacerbation Chronic Obstructive Pulmonary Disease / AECOPD

Research involving
Human

Sponsors and support

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

Intervention

Keyword: "Algorithms", "Emergency Service, "Exacerbation", "Pulmonary Disease, Chronic Obstructive", Hospital"

Outcome measures

Primary outcome

The primary endpoint is admission rate.

Secondary outcome

The secondary study endpoints are readmission rate, average length of stay when

admitted, healthcare costs, 30-day mortality rate and health status.

Study description

Background summary

In patients with an acute exacerbation of chronic obstructive pulmonary disease (AECOPD), no objective criteria are validated to decide which patient should be hospitalized or which can be treated at home. In the light of increasing healthcare costs together with the high prevalence of this condition, treatment of AECOPD should be restructured and optimized.

Study objective

The primary objective is to validate a previously established prognostic instrument in the form of an algorithm (flowchart) in patients that present with AECOPD to the department of emergency medicine for classifying for out- or inpatient treatment leading to less hospital admissions. The secondary objectives are demonstrating that this stratification also leads to less readmissions, shorter length of stay when admitted to the medical ward and efficient, cost-effective care without thereby adversely affecting health status and 30-day mortality rate.

Study design

Firstly the algorithm is validated in a prospective cohort. Secondly, a retrospective control group is compared to this prospective group stratified for treatment category by applying this flowchart. The primary endpoint is the admission rate, adjusted for health status and 30-days mortality. The secondary study endpoints are readmission rate, the average length of stay when admitted and healthcare costs.

Intervention

The algorithm is applied in all patients presenting to the emergency department with an acute exacerbation of COPD. It is divided into four categories based on clinical criteria and arterial blood gas values: discharge and treatment at home, admission to the medical ward, admission to the medical ward and start non-invasive ventilation or admission to the intensive care unit with or without (non-)invasive ventilation. All patients are evaluated between 5 to 10 days after inclusion in the outpatient clinic or, if still hospitalized, in the medical ward. CCQ and MRC questionnaires are carried out.

Study burden and risks

Participation in this study leads to therapeutic decision making based on objective parameters instead of a subjective funded decision. It is important to note that there is no actual difference between the nature of care provided in the medical ward and the care that could be provided at home. Therefore there is no increased risk in participation in this study. The expected benefit is avoidance of unnecessary admissions and in case of admission a shorter length of stay in the hospital.

Contacts

Public
HagaZiekenhuis

Leyweg 275
Den Haag 2545CH
NL
Scientific
HagaZiekenhuis

Leyweg 275
Den Haag 2545CH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient is previously diagnosed with COPD supported by spirometric evidence of airflow obstruction FEV1/VC < LLN), age > 35 years, smoking history (>1 Pack Year). Or diagnosed within three months after inclusion in stable pulmonary situation.
- Patient is presenting with a probable or certain exacerbation of COPD, defined as: An acute event characterized by a worsening of the patient*s respiratory symptoms that is beyond day-to-day variations and leads to a change in medication.

Exclusion criteria

- Active malignancy with life expectancy < 12 months
- Dyspnoea otherwise explained: e.g. pulmonary embolism, acute cardiac event, pneumothorax, etc.
- New consolidation on chest radiograph suggestive for pneumonia
- Comorbidity requiring hospitalization independent of severity of AECOPD: e.g. acute renal insufficiency, electrolyte disorder, decompensated heart failure, etc.
- The subject is incapacitated

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2015
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	12-10-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	18-07-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	12-02-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL54541.098.15