GOLD D in primary care: a group whose clinical outcomes can easily be improved

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON41773

Source
ToetsingOnline

Brief title
GOLD D in primary care

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Chronic Obstructive Pulmonary Disease, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Certe,Glaxo Smith Kline NL; Certe,GlaxoSmithKline

Intervention

Keyword: COPD, GOLD D, Integrated Care, Primary Care

Outcome measures

Primary outcome

Workpackage 1: describing patient characteristics (age, gender, smoking status, medication use and comorbidities) of group D patients in comparison to group A, B and C patients and the representativeness of group D on a global scale using the large database from the UNLOCK initiative.

Primary outcome in workpackage 1 is: a description of baseline characteristics of the primary care group D COPD patients

Workpackage 2: evaluating health status and exacerbation rate in group D patients after 12 months treatment in the AC service. This workpackage focusses on validating current identified phenotypes that are associated with clinically relevant improvement in health status, exacerbations, health care costs and medication use. Data from usual care from group A, B and C will be used as comparison.

Primary outcome in workpackage 2 is: the difference in health status between the baseline and final follow-up visit at 12 months as measured by the Clinical COPD Questionnaire (CCQ) and the COPD Assessment Test (CAT).

Secondary outcome

Workpackage1:

Secondary outcomes:

• A comparison of baseline characteristics of GOLD D patients with baseline

characteristics of the GOLD ABC patients

• Compare group D patients using either CCQ>=1 or CAT >=10.

• Evaluating the representativeness of the AC service patients on a global scale. By comparing the characteristics of the AC service patients with those of the UNLOCK initiative patients.

Workpackage 2:

Secondary outcomes:

• Identifying patient characteristics that are associated with a change in quality of life (thereby validating current identified patient phenotypes).

• Differences in number of exacerbations between the year preceding the study and the follow-up period.

• Differences in health care costs between the year preceding the study and the follow-up period.

• Differences in medication use between the year preceding the study and the follow-up period.

• Differences in patient characteristics of group D patients compared to group A, B and C patients.

• Identifying patient characteristics that dissociate between patients that change from group D to group A, B or C within the follow-up year and patients that remain in group D within that year. Using solely data from usual care, this will be evaluated as well for patients in groups A, B and C.

Study description

Background summary

A recently published study shows that the prevalence of patients receiving inhaled medication is low, with almost 50% of COPD patients in group D not being treated at all, indicating gross undertreatment. Further information on this group is very scarce, even though this group is prevalent in primary care. Providing adequate treatment, including appropriate medication, in an integrated care environment might greatly enhance health status and reduce exacerbations in this group.

Study objective

The aim of the current study is evaluation of the Certe A/C service system. This is achieved via 2 workpackages:

Workpackage 1 constitutes of describing patient characteristics (age, gender, current medication, smoking status and comorbidities) of group D patients in comparison to the GOLD A, B and C and describing representativity on a global scale. This will ascertain external validity of the results.

Workpackage 2 comprises of the evaluation of health status and exacerbation rate of group D patients before and after 12 months treatment in an integrated care system. The focus in workpackage 2 lies on individual patient centered treatment by validating current identified patient phenotypes. During the 12 months follow-up period, information will be collected regarding lung function, health status, medication use (type of medication, daily dose, device used and adherence), inhalation technique, exacerbations, health care costs (direct primary and secondary health care usage, medication costs and indirect costs related to lost work), QALYs and a full blood count (especially eosinophil and neutrophil). Additionally, data from usual care from group A, B and C will be used as comparison.

Study design

Design:
This study is an prospective observational study that will be performed at the department of primary care at the University Medical Center Groningen, the Groningen Research Institute for Asthma and COPD and the local laboratory, Certe .

Assessment of representativeness will be accomplished with use of the UNLOCK initiative comprised of datasets from: United Kingdom, the Netherlands, Sweden, Norway, Spain, Belgium, Greece, Ukraine, Canada and Australia.

Study burden and risks

Only the participants in workpackage 2 are subject to potentially additional burden and risks.

Visit 1, the venipuncture is associated with slight risks, they may include:
Excessive bleeding
Fainting or feeling light-headed
Hematoma (blood accumulating under the skin)

There are 3 extra telephone interviews, after 3 , 6 and 9 months. Each will last maximally 15 minutes.

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

- Age>40
- Diagnosis COPD (workpackage 1) and COPD group D (workpackage 2)

Exclusion criteria

- Asthma diagnosis, asthma/COPD overlap syndrome or other respiratory illnesses
- Inability to complete questionnaires due to either language difficulties or cognitive problems

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2015
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	04-03-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-07-2015
Application type:	Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL50820.042.14