Efficacy of Single inhaler Maintenance And Reliever Therapy (SMART) with Spiromax® budesonide/formoterol versus fixed dose treatment with Diskus® fluticasone/salmeterol in COPD

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This research proposal aims to investigate the efficacy of the SMART approach with budesonide/fomoterol versus fixed dose treatment with fluticasone/salmeterol in patients with COPD.

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

Summary

ID

NL-OMON44539

Source
ToetsingOnline

Brief title
SMART versus fixed dose treatment in COPD

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: Door een grant van TEVA Pharma,TEVA Pharma

Intervention

Keyword: COPD, Effectiveness, Fixed dose treatment, SMART

Outcome measures

Primary outcome

The primary endpoint is the reduction in number of exacerbations (moderately

severe ad severe exacerbation combined).

Secondary outcome

Secondary endpoints:

* Lung function (PEF, FEV1, FEV1/FVC, FVC, FEF25-75%, RV, TLC, RV/TLC, RV/TLC

%predicted);

* IOS measurements, R5, R20, R5-R20, X5, AX;

* Questionnaires (inhaler device satisfaction [PASAPQ and FSI-10], side effects

[ICQ], health status [CCQ and SGRQ] and CAT);

* Change of the lung microbiome in induced sputum (in a subset of patients);

* Moderately severe and severe exacerbations analyzed separately;

* Analysis of baseline clinical and targeted as well as genome-wide

gene-expression data to identify predictors for a favorable ICS treatment

response in COPD.

Study description

Background summary

Chronic obstructive pulmonary disease (COPD) is a leading cause of death worldwide and its morbidity and mortality are still rising. A symptom-driven maintenance and reliever therapy (SMART) with budesonide/formoterol is a frequently used treatment strategy in asthma. Several studies have shown that the SMART approach effectively reduces the number of asthma exacerbations when compared to a fixed maintenance dose of, e.g. fluticasone/salmeterol. In addition, larger improvements in lung function and symptoms have been observed in asthma patients with the SMART approach. Thus far, no studies have investigated the efficacy of the SMART approach in patients with COPD. We hypothesize that SMART treatment with budesonide/formoterol will be more effective than fluticasone/salmeterol fixed dose treatment in COPD.

Study objective

This research proposal aims to investigate the efficacy of the SMART approach with budesonide/fomoterol versus fixed dose treatment with fluticasone/salmeterol in patients with COPD.

Study design

This will be a randomized, parallel 2-arm, open-label, multi-centre study.

Intervention

COPD patients will be randomized to one of the following two treatment groups:
A: One year Spiromax® budesonide/formoterol 160/4.5 *g two inhalations twice daily + Spiromax® budesonide/formoterol 160/4.5 *g as needed with a maximum of 8 inhalations daily.
B: One year Diskus® fluticasone/salmeterol 500/50 *g one inhalation twice daily + salbutamol 100 *g as needed with a maximum of 8 inhalations daily.

Study burden and risks

This study has no specific benefits for the participating patients. The study also has no major risks.
Minor risks for participant in this study are:
* Nasal epithelium collection may cause a temporary nose bleed.
* Blood collection may cause bruising.
* All drugs may cause side effects. For further information about the side effects of Spiromax® budesonide/formoterol see page 29 of this protocol. For further information about the side effects of Diskus® fluticasone/salmeterol see page 42 of this protocol.
* Temporary quitting of anti-inflammatory inhalation medication may cause

worsening of the symptoms resulting in an exacerbation.

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 between 40 and 80 years
* Smoking history of > 10 pack years
* COPD patients with an FEV1 < 80% predicted either or not using inhaled corticosteroids.
* At least one COPD exacerbation for which oral prednisolone had to be prescribed during 2 years prior to inclusion in the study.

Exclusion criteria

* History of asthma.
* Exacerbation or respiratory tract infection during the last 4 weeks prior to randomization.
* Females of childbearing potential without an efficient contraception unless they meet the following definition of post-menopausal: 12 months of natural (spontaneous) amenorrhea or 6 months of spontaneous amenorrhea with serum FSH >40 mIU/mL or the use of one or more of the following acceptable methods of contraception:
a) Surgical sterilization (e.g. bilateral tubal ligation, hysterectomy).
b) Hormonal contraception (implantable, patch, oral, injectable).
c) Barrier methods of contraception: condom or occlusive cap (diaphragm or cervical/vault caps) with spermicidal foam/gel/cream/suppository.
d) Continuous abstinence.
* Periodic abstinence (e.g. calendar, ovulation, symptom-thermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception. Reliable contraception should be maintained throughout the study and for 30 days after study drug discontinuation.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2015
Enrollment:	260
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Seretide
Generic name:	salmeterol/fluticason
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Spiromax budesonide/formoterol
Generic name:	budesonide/formoterol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-01-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-02-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-08-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-02-2019
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
EudraCT	EUCTR2014-001563-12-NL
CCMO	NL48953.042.14