DB2116134: A randomized, multi-center, double-blind, double-dummy, parallel group study to evaluate the efficacy and safety of umeclidinium/vilanterol compared with fluticasone propionate/salmeterol over 12 weeks in subjects with COPD

Published: 05-02-2013
Last updated: 24-04-2024

Efficacy and safety.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON38572

Source
ToetsingOnline

Brief title
DB2116134

Condition

- Respiratory disorders NEC

Synonym
COPD

Research involving

Human

Sponsors and support

Primary sponsor: GlaxoSmithKline BV
Source(s) of monetary or material Support: GlaxoSmithKline BV

Intervention

Keyword: COPD, Seretide, umeclidinium, vilanterol

Outcome measures

Primary outcome

24-hour weighted-mean FEV1 on Treatment Day 84.

Secondary outcome

Trough FEV1 on day 85, adverse events.

Study description

Background summary

COPD is a disorder characterized by airflow obstruction and reduced maximum expiratory flow from the lungs that is not fully reversible. Previous clinical research has indicated that combining an inhaled muscarinic antagonist with a beta2-agonist is more effective than the individual components in managing stable COPD to improve lung function. Therefore, the development of a new product which combines both pharmacological approaches affords clear advantages.
Umeclidinium (GSK573719) is a longacting muscarinic antagonist which is devoped as a dry powder for inhalation in combination with the longacting beta2-agonist vilanterol (GW642444) as a combination product for once daily inhalation therapy.
In this study the effects of umeclidinium/vilanterol once daily will be compared to those of Seretide (fluticasone propionate/salmeterol) twice daily.

Study objective

Efficacy and safety.

Study design

Multicenter randomized double blind phase III parallel group study. Run-in period of 1-2 weeks.
Randomisation (1:1) to treatment with:
* umeclidinium/vilanterol (62,5/25 mcg) once daily
* Seretide (fluticasone propionate/salmeterol 500/50 mcg) twice daily
administration as inhaled dry powder formulation.
Treatment duration 12 weeks. Total study duration appox. 15 weeks.
Approx 710 patients randomized.

Intervention

Treatment with umeclidinium/vilanterol or Seretide.

Study burden and risks

Risk: Adverse effects of study medication.
Burden: 6 visits in 15 weeks plus 1 telephone contact. Duration 1-24 h (2 long measurement days of approx. 6 and 24 h), final visit may be performed by telephone.
Pulmonary function tests: 1x incl. reversibility. During every visit, thereof 2 visits with serial measurements during 6 and 24 h resp. During 24 h measurement overnight stay in hotel near hospital.
Physical examination 2x.
Optional pharmacogenetic research (saliva).
Pregnancy test (if relevant) 3x, ECG 1x. Questionnaires 4x.
Daily completion of diary.

Contacts

Public
GlaxoSmithKline BV

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* COPD patients *40 years of age (see protocol page 23 for details).
* (Ex) smokers, at least 10 pack years.
* Pre and post salbutamol FEV1/FVC ratio <70%.
* Post salbutamol FEV1 *30% and *70% of predicted.
* A score of at least 2 on the Modified Medical Research Council Dyspnea Scale.
* Safe contraception for women of childbearing potential.

Exclusion criteria

* Pregnancy.
* Bronchial asthma.
* Documented COPD exacerbation in the past 12 months.
* Hospitalization for COPD or pneumonia in the past 12 weeks.
* Significant ECG abnormalities (see protocol page 24 for details).
* Treatment with specified (mainly COPD) therapies within a specified time frame (see protocol page 24-25 for details).

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-03-2013
Enrollment:	65
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Seretide
Generic name:	fluticasone propionaat/salmeterol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	umeclidinium/vilanterol
Generic name:	umeclidinium/vilanterol

Ethics review

Approved WMO

Date:	05-02-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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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	EUCTR2012-000524-18-NL
CCMO	NL43355.060.13
Other	www.gsk-clinicalstudyregister.com; registratienummer n.n.b.