A Randomised, Double Blind, Double Dummy, Parallel Group Study Comparing UMEC/VI (A Fixed Combination Of Umeclidinium and Vilanterol) With Tiotropium In COPD Subjects Who Continue To Have Symptoms on Tiotropium (DB2116960)

Published: 06-06-2013
Last updated: 22-04-2024

Efficacy and safety.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON38952

Source
ToetsingOnline

Brief title
DB2116960

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, tiotropium, umeclidinium, vilanterol

Outcome measures

Primary outcome

Through FEV1 on Treatment Day 85.

Secondary outcome

Adverse events, FEV1 3 h post dose on day 84, other pulmonary function test

parameters, use of rescue medication, questionnaires.

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 developed 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 Spiriva (tiotropium) once daily.

Study objective

Efficacy and safety.

Study design

Multicenter randomized double blind phase IIIb parallel group study. Run-in period of 4 weeks on open-label tiotropium. Only patients with a certain level of COPD symptoms during the run-in period will be randomized.
Randomisation (1:1) to treatment with:
• umeclidinium/vilanterol (62,5/25 mcg) once daily
• tiotropium (18 mcg) once daily
administration as inhaled dry powder formulation.
Treatment duration 12 weeks. Total study duration appox.18 weeks.
Approx 670 patients.

Intervention

Treatment with umeclidinium/vilanterol or tiotropium.

Study burden and risks

Risk: Adverse effects of study medication.
Burden: 9 visits in 18 weeks. Duration 2-4 h, final visit in principle be performed by telephone.
Pulmonary function tests: 1x incl. reversibility. Tests during 7 visits, thereof 6 visits with serial measurements during 1 and 4 h resp.
Smoking cessation counselling
Physical examination 2x.
Optional pharmacogenetic research (saliva).
Pregnancy test (if relevant) 5x, ECG 1x. Questionnaires 5x.
Daily completion of diary (medication use, concomitant medical problems, concomitant medication).

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

• COPD patients >=40 years of age (see protocol page 26 for details).
• Treatment with tiotropium for at least 3 months prior to screening (see protocol page 26 for details).
• (Ex) smokers, at least 10 pack years.
• Pre and post salbutamol FEV1/FVC ratio <70%.
• Post salbutamol FEV1 >=50% 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, lactation.
• Bronchial asthma.
• More than 1 COPD exacerbation in the past 12 months. Exacerbation in the last 6 weeks.
• Significant ECG abnormalities (see protocol page 28 for details).
• Currently taking an inhaled corticosteroid as part of their maintenance treatment for COPD.
• Treatment with other specified (mainly COPD) therapies within a specified time frame (see protocol page 28-30 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:	Will not start
Enrollment:	45
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Spiriva
Generic name:	tiotropium
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	umeclidinium/vilanterol
Generic name:	umeclidinium/vilanterol

Ethics review

Approved WMO

Date:	06-06-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	09-07-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	02-09-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2012-005007-41-NL
CCMO	NL44971.060.13
Other	www.gsk-clinicalstudyregister.com; registratienummer n.n.b.