A phase III, 52 week, randomized, double-blind, 3-arm parallel group study, comparing the efficacy, safety and tolerability of the fixed dose triple combination FF/UMEC/VI with the fixed dose dual combinations of FF/VI and UMEC/VI, all administered once-daily in the morning via a dry powder inhaler in subjects with chronic obstructive pulmonary disease

Published: 03-06-2014
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Primary: To evaluate the efficacy of FF/UMEC/VI to reduce the annual rate of moderate and severe exacerbations compared with dual therapy of FF/VI or UMEC/VI in subjects with COPD.
Secondary: Long term safety and other efficacy parameters.

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

Summary

ID

NL-OMON45240

Source
ToetsingOnline

Brief title
CTT116855

Condition

- Respiratory disorders NEC

Synonym
COPD; chronic obstructive pulmonary disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: COPD, fluticasone furoate, umeclidinium, vilanterol

Outcome measures

Primary outcome

Rate of exacerbations.

Secondary outcome

FEV1, St George questionnaire, time to first exacerbation. Adverse events.

Study description

Background summary

Inhaled corticosteroids, long-acting ß2-agonists (LABA) and long-acting muscarinic receptor antagonists (LAMA) are essential drugs for the treatment of COPD. This triple therapy is widely used; in the US in over 25% of COPD patients. Various clinical trials have shown the benefits of the addition of a third drug (LABA or LAMA).
Fluticasone furoate (FF) is an inhaled corticosteroid, umeclidinium (UMEC) is a LAMA and vilanterol is a LABA. The sponsor is currently developing these three drugs in a once daily fixed combination as a dry powder for inhalation for the treatment of more severe COPD (Gold D).

Study objective

Primary: To evaluate the efficacy of FF/UMEC/VI to reduce the annual rate of moderate and severe exacerbations compared with dual therapy of FF/VI or UMEC/VI in subjects with COPD.
Secondary: Long term safety and other efficacy parameters.

Study design

Multicenter randomized double blind phase III parallel group study. Run-in period of 2 weeks.
Randomization (2:2:1) to treatment with:
* FF/UMEC/VI (100/62,5/25 mcg) once daily
* FF/VI (100/25 mcg) once daily
* UMEC/VI (62.5/25 mcg) once daily
administration as inhaled dry powder formulation.
Treatment duration 52 weeks.
Safety follow-up of 1 week.
Approx 10.000 randomized patients.

Intervention

Treatment with FF/UMEC/VI, FF/VI or UMEC/VI.

Study burden and risks

Risk: Adverse effects of study medication. Worsening COPD due to discontinuation of current medication.
Burden:
7 visits and 1 phone call in 1 year. Duration 3-4 hours.
Physical examination: 3 times.
Blood draw 15 ml 5 times.
ECG 4 times.
Pulmonary function test + reversibility every visit.
Chest X-ray (if not performed in past 3 months) once.
Pregnancy test (if relevant) 6 times.
Questionnaires (4) 4-5 times.
Daily completion of electronic and paper diary.
Optional pharmacogenetic research (6 ml blood once.

Contacts

Public
GlaxoSmithKline

Huis ter Heideweg 62

Zeist 3705LZ
NL
Scientific
GlaxoSmithKline

Huis ter Heideweg 62
Zeist 3705LZ
NL

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.
* (Ex) smokers, at least 10 pack years.
* Post salbutamol FEV1/FVC ratio <0,70.
* A score of *10 on the COPD Assessment Test (CAT).
* Post-bronchodilator FEV1 < 50% predicted normal and a documented history of * 1 moderate or severe COPD exacerbation in the previous 12 months OR a post-bronchodilator 50% *FEV1 < 80% predicted normal and a documented history of * 2 moderate exacerbations or a documented history of *1 severe COPD exacerbation (hospitalized) in the previous 12 months.
* Safe contraception for women of childbearing potential.

Exclusion criteria

* Pregnancy, lactation.
* Risk factors for pneumonia (see protocol page 33 for details).
* Abnormal Chest x-ray (see protocol page 33 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):	30-06-2014
Enrollment:	225
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Anoro
Generic name:	umeclidinium/vilanterol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	fluticasone furoaat/umeclidinium/vilanterol
Generic name:	fluticasone furoaat/umeclidinium/vilanterol
Product type:	Medicine
Brand name:	Relvar
Generic name:	fluticasone furoaat/vilanterol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-06-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-07-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-05-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-06-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-07-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	04-02-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-02-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-03-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-03-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-03-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-03-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-04-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-04-2017
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
Other	clinicaltrials.gov, registratienummer n.n.b.
EudraCT	EUCTR2013-003075-35-NL
CCMO	NL48046.060.14