A 24-Week, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of GSK573719/GW642444 Inhalation Powder and the Individual Components Delivered Once-Daily via a Novel Dry Powder Inhaler in Subjects with Chronic Obstructive Pulmonary Disease (DB2113361)

Published: 04-02-2011
Last updated: 27-04-2024

The primary objective of this study is to evaluate efficacy and safety. Secondary objectives: PK, PK-PD.

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

Summary

ID

NL-OMON36160

Source
ToetsingOnline

Brief title
DB2113361

Condition

- Respiratory disorders NEC

Synonym
COPD

Research involving
Human

Sponsors and support

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

Intervention

Keyword: COPD, GSK573719, GW642444

Outcome measures

Primary outcome

Change from baseline in trough FEV1 on Day 169.

Secondary outcome

PK, PK-PD.

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.
GSK573719 is a longacting muscarinic antagonist which is devoped as a dry powder for inhalation in combination with the longacting beta2-agonist GW642444 as a combination product (GSK573719/GW642444) for once daily inhalation therapy.
This study is one of two pivotal phase III studies. Efficacy and safety of the combination product iwill be compared to those of each of the individual components and placebo.

Study objective

The primary objective of this study is to evaluate efficacy and safety.
Secondary objectives: PK, PK-PD.

Study design

Multicenter randomized double blind phase III parallel group study en active and placebo control. Run-in period of 1-2 weeks.
Randomisation ((3:3:3:2) to treatment with:
1. GSK573719/GW642444 125/25 mcg OD
2. GSK573719 125mcg OD
3. GW642444 25 mcg OD
4. Placebo.
Administration as inhaled dry powder formulation.
Treatmnent duration 24 weeks. Total study duration appox. 27 weeks.
Approx 1460 patients, 100 in NL.

Intervention

Treatment with GSK573719/GW642444, GSK573719, GW642444 or placebo.

Study burden and risks

Risk: Adverse effects of study medication.
Burden: 9 visits in 27 weeks. Duration 1,5-8h (4 long measurement days of approx. 8 h). 1 phone call.
Pulmonary function tests: 1x incl. reversibility. During 8 visits serial measurements (4 visits: 2 tests in 1 h, 4 visits: 7 tests in approx. 7 h).
Blood tests (safety and/or PK) during 5 visits, 42 ml in total , pregnancy test (if relevant) 4x, ECGs during 4 vistis (thereof on 3 occasions 3 recordings).
Questionnaires 5x.
Daily completion of diary.
Optional: farmacogenetic research (10 ml blood).
Chest X-ray only if not performed in the past 6 months.

Contacts

Public
GlaxoSmithKline

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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.
• (Ex) smokers, at least 10 pack years.
• Post salbutamol FEV1/FVC ratio <70%.
• Post salbutamol FEV1 <=70% of predicted.
• A score of >=2 on the Modified Medical Research Council Dyspnea Scale at Visit 1.
• Safe contraception for women of childbearing potential.

Exclusion criteria

• Pregnancy.
• Bronchial asthma.
• Oral steroids in the past 6 weeks.
• Hospitalization for COPD or pneumonia in the past 12 weeks.
• Significant ECG abnormalities (see protocol for details).
• Treatment with specified (mainly COPD) therapies within a specified time frame (see protocol for details).
• Previous use of GSK573719, GW642444, the GSK573719/GW642444 combination or the Fluticasone Furoate/GW642444 combination.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2011
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	GSK573719
Generic name:	GSK573719
Product type:	Medicine
Brand name:	GSK573719/GW642444
Generic name:	GSK573719/GW642444
Product type:	Medicine
Brand name:	GW642444
Generic name:	GW642444

Ethics review

Approved WMO

Date:	04-02-2011

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-03-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-03-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-04-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-04-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-04-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-05-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-05-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	23-05-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-06-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-06-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-07-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-07-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-10-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-10-2011
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	EUCTR2010-023348-33-NL
CCMO	NL35607.060.11