A randomized, double-blind, double-dummy, parallel group, multicenter study of once daily Fluticasone Furoate/Vilanterol 100/25 mcg Inhalation Powder, twice daily Fluticasone Propionate/Salmeterol 250/50 mcg Inhalation Powder, and twice daily Fluticasone Propionate 250 mcg Inhalation Powder in the treatment of persistent asthma in adults and adolescents already adequately controlled on twice-daily inhaled corticosteroid and long-acting beta2 agonist (study 201378)

Published: 18-11-2014
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Primary: To demonstrate non-inferiority of RELVAR 100/25 once-daily to SERETIDE 250/50 twice-daily in adult and adolescent subjects 12 years of age and older with persistent asthma,adequately controlled on twice-daily ICS/LABA. Secondary: Adverse...

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

Summary

ID

NL-OMON44419

Source
ToetsingOnline

Brief title
study 201378

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma; bronchial asthma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: asthma, controlled, fluticasone furoate, vilanterol

Outcome measures

Primary outcome

Change from baseline in clinic visit evening FEV1 (pre-bronchodilator and

pre-dose) at the end of the 24-week treatment period.

Secondary outcome

Percentage of rescue-free and symptom-free 24-hour periods during the study,

peak flow, asthma control test, adverse events, exacerbations.

Study description

Background summary

RELVAR ELLIPTA (fluticasone furoate/vilanterol inhalation powder) is a inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) combination for oral inhalation administered from a dry powder inhaler approved in several countries including the EU for the treatment of asthma and COPD. In a number of countries including the EU the asthma indication is limited to patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists. The indication does not currently include patients already adequately controlled on both an ICS and LABA (also known as a substitution indication).
Obtaining a substitution indication would allow patients controlled with a twice daily ICS/LABA (as a combination product or via separate inhalers) to be switched to once daily RELVAR ELLIPTA, which would simplify their treatment regimen and encourage treatment compliance. This would also make the asthma indication for RELVAR approved in the EU and some other countries consistent with other approved ICS/LABA combinations in those countries. In order to support a substitution indication this study will determine if once daily RELVAR 100/25 is non-inferior to twice-daily SERETIDE (fluticasone propionate/salmeterol) 250/50 in adult and adolescent asthmatic subjects already adequately controlled on a twice-daily ICS/LABA. Fluticasone propionate 250 has been included as an active comparator for assay sensitivity.

Study objective

Primary: To demonstrate non-inferiority of RELVAR 100/25 once-daily to SERETIDE 250/50 twice-daily in adult and adolescent subjects 12 years of age and older with persistent asthma,
adequately controlled on twice-daily ICS/LABA.
Secondary: Adverse events, exacerbations.

Study design

Randomised, double-blind, double-dummy, parallel-group phase III non-inferiority study.
LABA washout 5 days. 4 week run-in period on SERETIDE 250/50 mcg twice daily.
Randomisation (1:1:1) to
* RELVAR ELLIPTA 10/25 mcg once daily for 24 weeks
* SERETIDE 250/50 mcg twice daily for 24 weeks
* FLIXOTIDE 250 mcg twice daily for 24 weeks.
Salbutamol rescue medication.
Follow-up: 1 week.
Approx. 1460 patients.

Intervention

Treatment with RELVAR, SERETIDE or FLIXOTIDE.

Study burden and risks

Risk: adverse events of study treatment.
Burden: 7 visits and 1 telephone call in 30 weeks. Duration 1-3 h.
Physical examination once.
Pregnancy test 4 times.
Pulmonary function test 7 times. Once incl. reversibility.
Peak expiratory flow twice daily.
Twice completion of 2 questionnaires.
Paper and electronic diary. Asthmatic complaints, rescue medication, other complaints and medication and level of exercise.
Optional pharmacogenetic testing (saliva)

Contacts

Public
GlaxoSmithKline

Huis te Heideweg 62
Zeist 3705 LZ
NL
Scientific
GlaxoSmithKline

Huis te Heideweg 62
Zeist 3705 LZ
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)

Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Outpatients *12 years of age with asthma (NIH 2007) for at least 12 weeks.
* Pre-bronchodilator FEV1 of *80% of the predicted normal value.
* Mid dose ICS plus LABA (equivalent to FP/salmeterol 250/50 twice daily or an equivalent combination via separate inhalers) for at least the 12 weeks immediately preceding Visit 1.
* In the opinion of the investigator the subject*s asthma is well controlled.
* Adequate contraception for females of childbearing potential (see protocol page 24-25 for details).

Exclusion criteria

* Life-Threatening Asthma within the last 5 years. See protocol page 25 for details.
* Respiratory infections, other concurrent diseases. See protocol page 25-26 for details.
* Severe milk protein allergy.
* Concomitant medications as listed in section 6.10 of the protocol.
* Immunosuppressive therapy.
* Current smokers or former smokers with a smoking history of *10 pack years.
* Pregnancy or breastfeeding

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):	28-04-2015
Enrollment:	56
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Flixotide
Generic name:	fluticasone propionate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Relvar Ellipta
Generic name:	fluticasone furoate/vilanterol
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Seretide
Generic name:	fluticasone propionate/salmeterol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	18-11-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-01-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-02-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	20-02-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-11-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-12-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-12-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-01-2016

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-01-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-01-2016
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)

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	EUCTR2014-002253-19-NL
CCMO	NL50556.060.14