A Randomised, Double-Blind, Double-Dummy, Parallel-Group, Multicentre Study to assess efficacy and safety of Fluticasone Furoate (FF)/GW642444 Inhalation Powder and Fluticasone Propionate FP)/Salmeterol Inhalation Powder in the Treatment of Persistent Asthma in Adults and Adolescents.

Published: 27-08-2010
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Primary: Efficacy of FF/GW642444 100/25 mcg once daily in comparison with that of FP/salmeterol 250/50 mcg twice daily during 24 weeks.Secundary: Safety and tolerability.

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

Summary

ID

NL-OMON34054

Source
ToetsingOnline

Brief title
HZA113091

Condition

- Bronchial disorders (excl neoplasms)

Synonym

Asthma, Persistent Asthma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Fluticasone Furoate, GW642444, Persistent Asthma

Outcome measures

Primary outcome

FEV1 0-4 h and at trough level.

Secondary outcome

Questionnaires quality of life, asthma control, healthcare utilization, adverse

events, cortisol excretion.

Study description

Background summary

Inhaled longacting *2-receptor agonists and inhaled steroids are the cornerstones of bronchial asthma treatment. They are also marketed as combinations.
The current combinations must be dosed twice daily.
Fluticasone furoate is a new glucocorticoid, being developed as an inhalation powder (in a newly designed inhaler. Preclinical and clinical tests indicate a longer duration of action in comparison with fluticasone propionate (marketed as Flixotide); so once daily dosing seems realistic. There is a need for once daily administration in order to improve treatment compliance and thus asthma control.
GW642444M is a potent, longacting *2-receptor agonist.
In this study efficacy and safety of the once daily combination fluticasone furoate and GW642444M is compared with the effects of a twice daily administration of fluticasone propionate and the longacting *2-agonist

salmeterol (Seretide).

Study objective

Primary: Efficacy of FF/GW642444 100/25 mcg once daily in comparison with that of FP/salmeterol 250/50 mcg twice daily during 24 weeks.
Secundary: Safety and tolerability.

Study design

Multicenter randomized double-blind double-dummy parallel Group phase III study.
Discontinuation of current asthma treatment. Run-in period of 4 weeks fluticasone propionate and salbutamol. Thereafter randomization (1:1) to:
1. Fluticasone furoate/GW642444 100/25 mcg once daily.
2. Fluticasone propionate/salmeterol 250/50 mcg twice daily.
24 treatment weeks.
Approx 820 randomized patients (approx 1640 to screen).

Intervention

Treatment with fluticasone furoate/GW642444 or fluticasone propionate/salmeterol.

Study burden and risks

Risk: Adverse events of study medication. Discontinuation of current asthma treatment.
Burden: 6 visits and 3 telephone calls in 24 weeks, incl. 2 long measurement days of 4 and 24 h. Overnight stay in hospital for 24 h measurements. All visits start between 5 and 9 pm.
Pulmonary function tests: at screening incl. reversibility. At 1st dose of study medication 8 tests in 1st 4 h. Last dose 17 tests in 24 h (incl. measurements during night). Other visits 1 test.
Blood tests 3x (approx 4-10 ml/visit, approx 20 ml in total). Optional pharmacogenetic study (10 ml of blood).
Physical examination 1x, ECG 1x, pregnancy test 3x, Astma control test 3x. AQLQ and EQ-5D questionnaires 2x.

Contacts

Public
GlaxoSmithKline

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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

* Age 12 years and above.
* Bronchial asthma (acc. to NIH), at least 12 weeks.
* Evening FEV1 of 40-85%.
* At least 12% and at least 200ml reversibility of FEV1.
* Inhaled corticosteroid for at least 12 weeks and be maintained on a medium dose (e.g. FP 250 mcg twice daily) for at least the last 4 weeks.
* Females of childbearing potential: reliable method of contraception.

Exclusion criteria

* Life-threatening asthma within the last 5 years.
* Respiratory infection within the last 4 weeks.
* Asthma exacerbation within the last 12 weeks.
* Visual evidence of candidiasis.
* History of severe milk protein allergy.

* Potent CYP3A4 inhibitor within the last 4 weeks.
* Current smoker or a smoking history of 10 pack years. Use of inhaled tobacco products within the past 3 months.
* 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):	28-10-2010
Enrollment:	62
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Avamys
Generic name:	fluticasone furoate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Flixotide
Generic name:	fluticasone propionaat
Registration:	Yes - NL outside intended use
Product type:	Medicine

Brand name:	GW642444
Generic name:	GW642444
Product type:	Medicine
Brand name:	Serevent
Generic name:	salmeterol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ventolin
Generic name:	salbutamol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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 nog niet bekend
EudraCT	EUCTR2010-019589-10-NL

Register	ID
CCMO	NL32720.098.10