HZA116863: A Randomized, Double-Blind, Parallel Group, Multicenter Study of Fluticasone Furoate/Vilanterol 200/25 mcg Inhalation Powder, Fluticasone Furoate/Vilanterol 100/25 mcg Inhalation Powder, and Fluticasone Furoate 100 mcg Inhalation Powder in the Treatment of Persistent Asthma in Adults and Adolescents (HZA116863)

Published: 30-08-2012
Last updated: 26-04-2024

Primary: to compare the efficacy and safety of once daily (evening) administration of FF/VI 100/25 with FF 100 in adult and adolescent subjects >= 12 years of age with moderate to severe, persistent bronchial asthma over 12 weeks.Secondary:...

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

Summary

ID

NL-OMON40121

Source
ToetsingOnline

Brief title
HZA116863

Condition

- Bronchial disorders (excl neoplasms)

Synonym
bronchial asthma; asthma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: asthma, Fluticasone Furoate, Vilanterol

Outcome measures

Primary outcome

Weighted mean serial FEV1 over 0-24 hours post-dose at the end of the treatment period.

Secondary outcome

Major secondary variables: Change from baseline in the percentage of symptom-free 24-hour periods during the treatment period, change from baseline in AM and PM PEF averaged over the treatment period, adverse events, exacerbations, candidiasis.

Study description

Background summary

Inhaled long acting β2-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 (FF)/Vilanterol (VI) is a combination of a glucocorticoid and a long-acting beta2-agonist (LABA) currently under development for use as a once daily inhaled treatment for asthma and COPD. International guidelines advocate the use of inhaled LABAs in combination with ICS as maintenance therapy for asthmatics who remain symptomatic on low- to mid-doses of ICS. The availability of a once daily ICS/LABA treatment would be expected to improve patient compliance and, consequently, improve asthma control.
Current asthma guidelines also suggest that for patients not adequately controlled on low or medium dose ICS combined with a LABA, *stepping up* to a higher dose of the ICS in the combination product may be warranted. Thus, it is clinically important to identify patients who may benefit from the higher strength ICS/LABA combination product.

Study objective

Primary: to compare the efficacy and safety of once daily (evening) administration of FF/VI 100/25 with FF 100 in adult and adolescent subjects >= 12 years of age with moderate to severe, persistent bronchial asthma over 12 weeks.
Secondary: relative efficacy of Fluticasone Furoate/Vilanterol 200/25mcg and Fluticasone Furoate/Vilanterol 100/25.

Study design

Multicenter randomized double-blind parallel group phase III study.
Discontinuation of current asthma treatment. Run-in period 4 weeks. Thereafter randomization (1:1:1) to:
1. FF/VI Inhalation Powder 200/25 once daily in the evening
2. FF/VI Inhalation Powder 100/25 once daily in the evening
3. FF 100 Inhalation Powder once daily in the evening
Salbutamol rescue medication.
Study duration max. 17 weeks (run-in max. 4 w, treatment 12 w, follow-up 1 w).
Approx 990 randomized patients.

Intervention

Treatment with fluticasone furoate/ Vilanterol or fluticasone furoate.

Study burden and risks

Risk: Adverse events of study medication. Discontinuation of current asthma treatment.
Burden: 8 visits in 17 weeks, incl. 1 long measurement day of 24 h. All visits start between 4 and 5 PM.
Physical examination 2x.
Blood tests (17,5 ml) 2x.

Pulmonary function tests: at screening incl. reversibility. 3x 1 test. 14 tests during visit 7 in 24 h.
It may be necessary for practical reasons to arrange an overnight stay for the patiënt for the day with 24h measurements. In principle this will not be in the hospital, but in an accomodation nearby. For this reason qustion E3 has been answered in a negatively.
Daily peak flow AM and PM.
ECG 1x.
Pregnancy test 1-2x.
Diary completion daily.
Questionnaires 5x.

Contacts

Public
GlaxoSmithKline BV

Huis ter Heideweg 62
Zeist 3705 LZ
NL
Scientific
GlaxoSmithKline BV

Huis ter Heideweg 62
Zeist 3705 LZ
NL

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.
• Best FEV1 of 40-80% (pre-bronchodilator). See protocol page 19 for details.
• At least 12% and at least 200ml reversibility of FEV1.
• Inhaled corticosteroid for at least 12 weeks. See protocol page 20 for details.
• 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. No inhaled tobacco products within the past 3 months.
• Previous use of FF/VI of FF in another phase III study.
• 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):	22-11-2012
Enrollment:	35
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Fluticasone Furoate
Generic name:	Fluticasone Furoate
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Fluticasone Furoate/Vilanterol
Generic name:	Fluticasone Furoate/Vilanterol

Ethics review

Approved WMO Date:	30-08-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-10-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-03-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-03-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	03-05-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-08-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-08-2013
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
Other	clinicaltrials.gov; registratienummer n.n.b.
EudraCT	EUCTR2012-002797-32-NL
CCMO	NL41863.060.12