A randomised, double-blind, double-dummy, placebo controlled multi-centre study to evaluate the efficacy and safety of fluticasone furoate inhalation powder and fluticasone propionate inhalation powder in the treatment of asthma in adults and adolescents not currently treated with inhaled corticosteroids (FFA115285)

Published: 19-08-2011
Last updated: 28-04-2024

Efficacy and safety during 24 treatment weeks.

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

Summary

ID

NL-OMON37429

Source
ToetsingOnline

Brief title
FFA115285

Condition

- Respiratory disorders NEC

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, efficacy, fluticasone, furoate

Outcome measures

Primary outcome

Change in trough level FEV1 in week 24 compared to baseline.

Secondary outcome

Change compared to baseline in number of days without rescue medication,

peakflow, symptom free days, asthma control, healthcare utilization, adverse

events, exacerbations.

Study description

Background summary

Inhaled steroids are, together with inhaled longacting β2-receptor agonists, the cornerstones of bronchial asthma treatment. They are also marketed as combinations.
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.
In this study efficacy and safety of once daily fluticasone furoate 50 mcg is compared with the effects of a twice daily administration of fluticasone

propionate and placebo in adolescents and adults, who are presently not using a corticosteroid. Since there are many adolescents with asthma, data on the effects in the age group of 12 years and above are also collected in this study. The dose of the inhaled corticosteroid in this age group is not different from the dose in adults.

Study objective

Efficacy and safety during 24 treatment weeks.

Study design

Multicenter randomized double-blind double-dummy parallel group phase III study.
Run-in period of 2 weeks. Thereafter randomization (1:1:1) to inhaled:
1. Fluticasone furoate (FF) 50 mcg once daily.
2. Fluticasone propionate (FP) 100 mcg twice daily.
3. Placebo.
24 treatment weeks.
Double dummy design because FF is provided in a new dry powderinhaler (Novel Powder Inhaler) and FP in the well-known DISKUS (ACCUHALER).
Approx 330 randomized patients (approx 20 in NL).

Intervention

Treatment with fluticasone furoate or fluticasone propionate.

Study burden and risks

Risk: Adverse effects of study medication.
Burden: 8 visits en 3 phone calls in 27 weeks. All visits late in the afternoon or evening.
Physical examination 2x.
Blood tests 2x (15-20 ml blood).
Optional pharmacogenetic tests (10 ml blood).
Pregnancy test (if indicated) 4x.
Pulmonary function test 8x (once incl. reversibility).
Peak flow measurements and completion of electronic diary daily 2x.
3 questionnaires (QoL, asthma control) 4x (time needed approx. 15 min).

Contacts

Public
GlaxoSmithKline

Huis ter Heideweg 62
Zeist 3705 LZ
NL
Scientific
GlaxoSmithKline

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.
• Evening FEV1 of at least 60% of normal.
• At least 12% and at least 200 ml reversibility of FEV1.
• Current anti-asthma treatment: non-corticosteroid controller and/or short-acting bronchodilator.
• Females of childbearing potential: reliable method of contraception.

Exclusion criteria

• Life-threatening asthma within the last 10 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.
• 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:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-12-2011
Enrollment:	20
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:	fluticasone furoate
Generic name:	fluticasone furoate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	19-08-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-09-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-10-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-10-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-01-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	16-01-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-01-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-08-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-08-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-01-2013
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; regsitratienummer n.n.b.
EudraCT	EUCTR2011-001900-36-NL
CCMO	NL37837.060.11