Clinical trial results:
Clinical assessment of GW815SF Salmeterol/fluticasone propionate (HFA MDI) in pediatric patients with bronchial asthma -A long term (24-week) study

Summary

EudraCT number	2015-004881-27
Trial protocol	Outside EU/EEA
Global end of trial date	24 November 2007

Results information

Result version number	v1 (current)
This version publication date	14 January 2017
First version publication date	14 January 2017

Trial information

Trial identification

Sponsor protocol code	110101

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	18 February 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 November 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

TBD

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 March 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Japan: 40
Worldwide total number of subjects	40
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	35
Adolescents (12-17 years)	5
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment
Recruitment details: -

Pre-assignment
Screening details: -

Pre-assignment period milestones	
Number of subjects started	40
Number of subjects completed	40

Period 1	
Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Salmeterol/fluticasone propionate

Arm description:

Salmeterol/fluticasone propionate patients received 2 inhalations twice daily each inhalation was 25/50mcg for 24 weeks(Total daily dose was 100/200mcg)

Arm type	Experimental
Investigational medicinal product name	Salmeterol/fluticasone propionate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder
Routes of administration	Oral use

Dosage and administration details:

Two inhalations twice daily

Number of subjects in period 1	Salmeterol/fluticasone propionate
Started	40
Completed	40

Baseline characteristics

Reporting groups	
Reporting group title	Salmeterol/fluticasone propionate
Reporting group description:	
Salmeterol/fluticasone propionate patients received 2 inhalations twice daily each inhalation was 25/50mcg for 24 weeks(Total daily dose was 100/200mcg)	

Reporting group values	Salmeterol/fluticasone propionate	Total	
Number of subjects	40	40	
Age categorical Units: Subjects			
Age continuous			
Age continuous description			
Units: years			
arithmetic mean	8.7		
standard deviation	± 2.5	-	
Gender categorical			
Gender categorical description			
Units: Subjects			
Female	16	16	
Male	24	24	
Race/Ethnicity, Customized			
One participant counted twice due to having multiple races.			
Units: Subjects			
Asian	40	40	

End points

End points reporting groups

Reporting group title	Salmeterol/fluticasone propionate

Reporting group description:

Salmeterol/fluticasone propionate patients received 2 inhalations twice daily each inhalation was 25/50mcg for 24 weeks(Total daily dose was 100/200mcg)

Primary: Most Frequent Adverse Events - On Therapy

End point title	Most Frequent Adverse Events - On Therapy[1]

End point description:

Adverse events, Clinical laboratory tests, Adrenocortical function test, Physical examinations, 12-lead electrocardiogram (ECG), Oropharyngeal examination were included.

End point type	Primary

End point timeframe:

Baseline to Week 24

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There are no statistical data to report.

End point values	Salmeterol/fluticasone propionate			
Subject group type	Reporting group			
Number of subjects analysed	40[2]			
Units: Participants				
Laryngopharyngitis	8			
Bronchitis	8			
Nasopharyngitis	8			
Asthma	8			
Pharyngitis	6			
Pyrexia	5			
Otitis media	4			
Pharyngotonsillitis	3			
Laryngotracheo bronchitis	3			
Molluscum contagiosum	3			
Stomatitis	3			

Notes:

[2] - Safety analysis was performed on the primary outcome measures, adverse events and safety population

Statistical analyses

No statistical analyses for this end point

Primary: Serious Adverse Events (SAEs) - On Therapy

End point title	Serious Adverse Events (SAEs) - On Therapy[3]

End point description:

Number of participants considered by the investigator to be related to study medication. Adverse events, Clinical laboratory tests, Adrenocortical function test, Physical examinations, 12-lead ECG,

Oropharyngeal examination were included. Frequency threshold of reported SAE's is 0%(100% reported)

End point type	Primary

End point timeframe:

Baseline to Week 24

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There are no statistical data to report.

End point values	Salmeterol/fluticasone propionate			
Subject group type	Reporting group			
Number of subjects analysed	40[4]			
Units: Participants	1			

Notes:

[4] - Safety population, all who entered
treatment period and received at least 1 dose of study med

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Morning Peak Expiratory Flow (PEF) During Weeks 1-24

End point title	Change from Baseline in Morning Peak Expiratory Flow (PEF) During Weeks 1-24

End point description:

PEF taken daily and average used for week 1-24 value. The peak expiratory flow rate measures how fast a person can (exhale) air. Then, compares it to normal flow rates to predict obstruction and disease. The average PEF for a child or adolescent whose height is 43" is 147 L/min, whose height is 66" is 454 L/min.

End point type	Secondary

End point timeframe:

Baseline and during Weeks 1-24

End point values	Salmeterol/fluticasone propionate			
Subject group type	Reporting group			
Number of subjects analysed	40[5]			
Units: L/min				
arithmetic mean (standard deviation)	32.9 (± 34.48)			

Notes:

[5] - Efficacy analyses were performed on the secondary outcome measures and Full analysis set

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Percent Predicted Morning Peak Expiratory

Flow (PEF) During Weeks 1-24

End point title	Change from Baseline in Percent Predicted Morning Peak Expiratory Flow (PEF) During Weeks 1-24

End point description:

Percent Predicted Morning Peak Expiratory flow were the percent of patients that were predicted to have their Peak expiratory flow in the morning.

End point type	Secondary

End point timeframe:

Baseline and during Weeks 1-24

End point values	Salmeterol/fluticasone propionate			
Subject group type	Reporting group			
Number of subjects analysed	40[6]			
Units: Percent Change				
arithmetic mean (standard deviation)	12.5 (± 11.294)			

Notes:

[6] - Efficacy analyses were performed on the secondary outcome measures and Full analysis set

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Evening Peak Expiratory Flow (PEF) During Weeks 1-24

End point title	Change from Baseline in Evening Peak Expiratory Flow (PEF) During Weeks 1-24

End point description:

The peak expiratory flow rate measures how fast a person can (exhale) air. Then compares it to normal flow rates to predict obstruction and disease. The average PEF for a child or adolescent whose height is 43" is 147 L/min, whose height is 66" is 454 L/min.

End point type	Secondary

End point timeframe:

Baseline and during Weeks 1-24

End point values	Salmeterol/fluticasone propionate			
Subject group type	Reporting group			
Number of subjects analysed	40[7]			
Units: L/min				
arithmetic mean (standard deviation)	31.2 (± 29.28)			

Notes:

[7] - Efficacy analyses were performed on the secondary outcome measures and Full analysis set

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Circadian Variation in Peak Expiratory Flow (PEF) During Weeks 1-24

End point title	Change from Baseline in Circadian Variation in Peak Expiratory Flow (PEF) During Weeks 1-24

End point description:

Circadian Variation means the various changes in a day. The peak expiratory flow rate measures how fast a person can (exhale) air using a mini-Wright peak flow meter. The average PEF for a child or adolescent whose height is 43" is 147 L/min, whose height is 66" is 454 L/min.

End point type	Secondary

End point timeframe:

Baseline and during Weeks 1-24

End point values	Salmeterol/fluticasone propionate			
Subject group type	Reporting group			
Number of subjects analysed	40[8]			
Units: Percent Change				
arithmetic mean (standard deviation)	-1.62 (± 3.583)			

Notes:

[8] - Efficacy analyses were performed on the secondary outcome measures and Full analysis set

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Symptom-Free Nights and Days

End point title	Number of Participants with Symptom-Free Nights and Days

End point description:

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Salmeterol/fluticasone propionate			
Subject group type	Reporting group			
Number of subjects analysed	40[9]			
Units: Participants				
Baseline	29			
Week 24	31			

Notes:
[9] - Efficacy analyses were performed on the secondary outcome measures and Full analysis set

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Rescue Medication-Free Nights and Days

End point title	Number of Participants with Rescue Medication-Free Nights and Days

End point description:
Rescue free means without the use of other medication.

End point type	Secondary

End point timeframe:
Baseline and Week 24

End point values	Salmeterol/fluticasone propionate			
Subject group type	Reporting group			
Number of subjects analysed	40[10]			
Units: Participants				
Baseline	33			
Week 24	32			

Notes:
[10] - Efficacy analyses were performed on the secondary outcome measures and Full analysis set

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: AEs and SAEs were monitored throughout the 24 weeks of treatment	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	10.0
Reporting groups	
Reporting group title	Salmeterol/fluticasone propionate
Reporting group description: Salmeterol/fluticasone propionate patients received 2 inhalations twice daily each inhalation was 25/50mcg for 24 weeks(Total daily dose was 100/200mcg)	

Serious adverse events	Salmeterol/fluticasone propionate		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 40 (2.50%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative dictionary used: MedDRA 10.0			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Salmeterol/fluticasone propionate		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	35 / 40 (87.50%)		
General disorders and administration site conditions			
Pyrexia			
alternative dictionary used: MedDRA 10.0			
subjects affected / exposed	5 / 40 (12.50%)		
occurrences (all)	5		

Gastrointestinal disorders Abdominal pain alternative dictionary used: MedDRA 10.0 subjects affected / exposed occurrences (all) Acetonaemic vomiting alternative dictionary used: MedDRA 10.0 subjects affected / exposed occurrences (all) Stomatitis alternative dictionary used: MedDRA 10.0 subjects affected / exposed occurrences (all)	 2 / 40 (5.00%) 2 2 / 40 (5.00%) 2 3 / 40 (7.50%) 3		
Respiratory, thoracic and mediastinal disorders Asthma alternative dictionary used: MedDRA 10.0 subjects affected / exposed occurrences (all)	 8 / 40 (20.00%) 13		
Skin and subcutaneous tissue disorders Eczema alternative dictionary used: MedDRA 10.0 subjects affected / exposed occurrences (all) Heat Rash alternative dictionary used: MedDRA 10.0 subjects affected / exposed occurrences (all)	 2 / 40 (5.00%) 2 2 / 40 (5.00%) 2		
Infections and infestations Bronchitis alternative dictionary used: MedDRA 10.0 subjects affected / exposed occurrences (all) Gastroenteritis alternative dictionary used: MedDRA 10.0	 8 / 40 (20.00%) 8		

subjects affected / exposed	2 / 40 (5.00%)			
occurrences (all)	3			
Laryngopharyngitis				
alternative dictionary used: MedDRA 10.0				
subjects affected / exposed	8 / 40 (20.00%)			
occurrences (all)	17			
Laryngotracheo bronchitis				
alternative dictionary used: MedDRA 10.0				
subjects affected / exposed	3 / 40 (7.50%)			
occurrences (all)	4			
Molluscum contagiosum				
alternative dictionary used: MedDRA 10.0				
subjects affected / exposed	3 / 40 (7.50%)			
occurrences (all)	4			
Nasopharyngitis				
alternative dictionary used: MedDRA 10.0				
subjects affected / exposed	8 / 40 (20.00%)			
occurrences (all)	14			
Otitis Media				
alternative dictionary used: MedDRA 10.0				
subjects affected / exposed	4 / 40 (10.00%)			
occurrences (all)	4			
Pharyngitis				
alternative dictionary used: MedDRA 10.0				
subjects affected / exposed	6 / 40 (15.00%)			
occurrences (all)	7			
Pharyngotonsillitis				
alternative dictionary used: MedDRA 10.0				
subjects affected / exposed	3 / 40 (7.50%)			
occurrences (all)	3			
Sinusitus				
alternative dictionary used: MedDRA 10.0				
subjects affected / exposed	2 / 40 (5.00%)			
occurrences (all)	2			

tonsillitus alternative dictionary used: MedDRA 10.0 subjects affected / exposed occurrences (all)	 2 / 40 (5.00%) 2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported