Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center Study to Evaluate the Efficacy and Safety of Fluticasone Furoate Nasal Spray for 2 Weeks in Chinese Adult and Adolescent subjects with Allergic Rhinitis

Summary

EudraCT number	2015-004889-28
Trial protocol	Outside EU/EEA
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	22 January 2017
First version publication date	22 January 2017

Trial information

Trial identification

Sponsor protocol code	113342

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?	Yes

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	31 August 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	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	22 September 2009
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	China: 365
Worldwide total number of subjects	365
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)	0
Adolescents (12-17 years)	16
Adults (18-64 years)	349
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Out of the 365 randomized patients, two patients did not take any study dose and are not considered for the baseline characteristics.

Pre-assignment

Screening details:

A total of 365 participants were screened and randomized into the study

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	FFNS 110 mcg

Arm description:

Fluticasone Furoate Nasal Spray (FFNS) 110 micrograms (mcg) once daily (QD)

Arm type	Experimental
Investigational medicinal product name	Fluticasone Furoate Nasal Spray (FFNS)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Nasal use

Dosage and administration details:

FFNS was provided as an aqueous suspension, with each spray delivering approximately 27.5 µg (micrograms) of fluticasone furoate. Four sprays (two in each nostril), equivalent to 110 mcg, were administered in the morning, once daily for 2 weeks.

Arm title	Placebo

Arm description:

Matching Vehicle Placebo Nasal Spray QD

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Nasal use

Dosage and administration details:

Four sprays (two in each nostril), of the FFNS-matching placebo, were administered in the morning, once daily for 2 weeks. The placebo contained only the vehicle used in FFNS.

Number of subjects in period 1[1]	FFNS 110 mcg	Placebo
Started	181	182
Completed	177	176
Not completed	4	6
Consent withdrawn by subject	2	1
Adverse event, non-fatal	-	1
Lost to follow-up	1	2
Protocol deviation	1	2

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Out of the 365 worldwide randomized participants, two participants did not take any study dose and are not considered in the baseline characteristics.

Baseline characteristics

Reporting groups	
Reporting group title	FFNS 110 mcg
Reporting group description:	
Fluticasone Furoate Nasal Spray (FFNS) 110 micrograms (mcg) once daily (QD)	
Reporting group title	Placebo
Reporting group description:	
Matching Vehicle Placebo Nasal Spray QD	

Reporting group values	FFNS 110 mcg	Placebo	Total
Number of subjects	181	182	363
Age categorical Units: Subjects			
Age continuous			
Baseline characteristics are summarized for the Full Analysis Set (FAS), comprised of all participants who were randomized and received at least one dose of study medication.			
Units: years			
arithmetic mean	31.8	33	
standard deviation	± 10.72	± 10.95	-
Gender categorical			
Gender categorical description			
Units: Subjects			
Female	97	99	196
Male	84	83	167
Race/Ethnicity, Customized Units: Subjects			
Chinese	181	182	363
Not Chinese	0	0	0

End points

End points reporting groups

Reporting group title	FFNS 110 mcg
Reporting group description:	
Fluticasone Furoate Nasal Spray (FFNS) 110 micrograms (mcg) once daily (QD)	
Reporting group title	Placebo
Reporting group description:	
Matching Vehicle Placebo Nasal Spray QD	

Primary: Mean change from baseline over the entire treatment period in the daily reflective total nasal symptom score (rTNSS)

End point title	Mean change from baseline over the entire treatment period in the daily reflective total nasal symptom score (rTNSS)
End point description:	
The Total Nasal Symptom Score (TNSS; possible score of 0-12) is the sum of 4 individual participant-assessed symptom scores for rhinorrhea, nasal congestion, nasal itching, and sneezing, each evaluated using a scale of 0=None, 1=Mild, 2=Moderate, or 3=Severe. The rTNSS was performed in the morning (AM rTNSS) and evening (PM rTNSS) and assessed the participant's symptoms over the preceding 12 hours. The daily rTNSS is the average of the AM rTNSS and PM rTNSS assessments. Mean changes from baseline over the entire treatment period were calculated as treatment period rTNSS minus baseline rTNSS.	
End point type	Primary
End point timeframe:	
Baseline through entire treatment period (Day 1 through Day 14)	

End point values	FFNS 110 mcg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	179[1]	178[2]		
Units: Points on a scale				
least squares mean (standard error)	-4.226 (± 0.1646)	-2.728 (± 0.1656)		

Notes:

[1] - Full Analysis Set (FAS):All participants who were randomized and received 1 dose of study medication

[2] - Full Analysis Set (FAS):All participants who were randomized and received 1 dose of study medication

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	FFNS 110 mcg v Placebo
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.498

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.897
upper limit	-1.009

Secondary: Mean change from baseline (Visit 2) to the end of study (Visit 4/Early Withdrawal) in nasal finding score by rhinoscopy

End point title	Mean change from baseline (Visit 2) to the end of study (Visit 4/Early Withdrawal) in nasal finding score by rhinoscopy

End point description:

The nasal finding score by rhinoscopy (possible score of 0-12) is the sum of 4 individual investigator assessed scores for swelling of inferior nasal concha mucosa, color of inferior nasal concha mucosa, watery secretion volume, and description of rhinorrhea. The symptoms were assessed using a scale of 0=None, 1=Mild, 2=Moderate, 3=Severe. Mean change from baseline to the end of study in nasal finding score by rhinoscopy was calculated as the nasal finding score by rhinoscopy at Visit 4/Early Withdrawal minus the nasal final finding score by rhinoscopy at Visit 2.

End point type	Secondary

End point timeframe:

Baseline through end of study (Day 1 through Day 15/Early Withdrawal)

End point values	FFNS 110 mcg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176[3]	177[4]		
Units: Points on a scale				
least squares mean (standard error)	-4.2 (± 0.22)	-2.9 (± 0.22)		

Notes:

[3] - FAS Population. Only participants for whom both baseline and post-baseline data were available.

[4] - FAS Population. Only participants for whom both baseline and post-baseline data were available.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline (Visit 2) to the end of study (Visit 4/Early Withdrawal) in severity of overall interference in activities of daily living

End point title	Mean change from baseline (Visit 2) to the end of study (Visit 4/Early Withdrawal) in severity of overall interference in activities of daily living

End point description:

The severity of overall interference in activities of daily living at baseline and the end of study was assessed by the investigator on the scale of 0=None, 1=Mild, 2=Moderate, 3=Severe. The mean change from baseline to the end of study in severity of overall interference in activities of daily living was calculated as the severity of overall interference in activities of daily living at Visit 4/Early Withdrawal minus severity of overall interference in activities of daily living at Visit 2.

End point type	Secondary

End point timeframe:

Baseline through end of study (Day 1 through Day 15/Early Withdrawal)

End point values	FFNS 110 mcg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	160[5]	165[6]		
Units: Points on a scale				
least squares mean (standard error)	-1.2 (± 0.07)	-0.8 (± 0.07)		

Notes:

[5] - FAS Population. Only participants for whom both baseline and post-baseline data were available.

[6] - FAS Population. Only participants for whom both baseline and post-baseline data were available.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All AE data from the time of participants randomization until the follow-up period (approximately 20 days) were collected.

Adverse event reporting additional description:

Serious and non-serious adverse events were collected in the Safety Set, comprised of all participants who were randomized and received at least one dose of study medication.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	13.0

Reporting groups

Reporting group title	FFNS 110 mcg

Reporting group description:

Fluticasone Furoate Nasal Spray (FFNS) 110 micrograms (mcg) once daily (QD)

Reporting group title	Placebo

Reporting group description:

Matching Vehicle Placebo Nasal Spray QD

Serious adverse events	FFNS 110 mcg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 181 (0.00%)	0 / 182 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	FFNS 110 mcg	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 181 (0.00%)	0 / 182 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: None of the participants had any non-serious AE at or above 5%

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