



## Clinical trial results:

### **A Pilot, Randomised, Double-blind, Placebo-controlled, Parallel-group, Multicentre Study to Evaluate the Efficacy and Safety of Once-daily Intranasal Administration of Fluticasone Furoate Nasal Spray 110 mcg for 4 Weeks in Adults and Adolescents with Irritant (Non-Allergic) Rhinitis**

#### **Summary**

EudraCT number	2015-004888-37
Trial protocol	Outside EU/EEA
Global end of trial date	10 February 2009

#### **Results information**

Result version number	v1 (current)
This version publication date	26 January 2017
First version publication date	26 January 2017

#### **Trial information**

##### **Trial identification**

Sponsor protocol code	FFR111158
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##### **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	Final
Date of interim/final analysis	06 May 2009
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	10 February 2009
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	12 March 2008
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	Thailand: 102
Worldwide total number of subjects	102
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)	3
Adults (18-64 years)	99
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 147 participants were screened, of which 102 participants were 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	Investigator, Subject

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Placebo

Arm description:

Vehicle placebo nasal spray once daily

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:

FFNS-matching placebo nasal spray, containing only the vehicle, was administered once daily for 4 weeks.

<b>Arm title</b>	FFNS 110 mcg
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Arm description:

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

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 a suspension containing 0.05% weight by weight of micronized fluticasone furoate. Each spray of the suspension delivered approximately 27.5 micrograms (mcg) of fluticasone furoate. Four sprays (two in each nostril), equivalent to 110 mcg, were administered in the morning, once daily for 4 weeks.

<b>Number of subjects in period 1</b>	Placebo	FFNS 110 mcg
Started	49	53
Completed	45	48
Not completed	4	5
Withdrew Consent	-	1
Adverse event, non-fatal	2	-
Protocol Deviation	1	2
Lost to follow-up	-	1
Lack of efficacy	1	1

## Baseline characteristics

### Reporting groups

Reporting group title	Placebo
Reporting group description:	
Vehicle placebo nasal spray once daily	
Reporting group title	FFNS 110 mcg
Reporting group description:	
Fluticasone Furoate Nasal Spray (FFNS) 110 micrograms (mcg) once daily	

Reporting group values	Placebo	FFNS 110 mcg	Total
Number of subjects	49	53	102
Age categorical			
Units: Subjects			

Age continuous			
Participants must have been 12 years of age or older.			
Units: years			
arithmetic mean	35.9	37.1	-
standard deviation	± 10.89	± 12.78	-
Gender categorical			
Gender categorical description			
Units: Subjects			
Female	37	33	70
Male	12	20	32
Race/Ethnicity, Customized			
Units: Subjects			
Asian	49	53	102
Other - Daily Reflective TNSS			
Total Symptom Scores (scale of 0-9; sum of the three individual nasal or ocular scores) based on 3 nasal symptoms (rhinorrhea, nasal congestion, and post-nasal drip) and 3 ocular symptoms (eye itching/burning, eye tearing/watering, and eye redness). Symptoms were evaluated on a scale of 0 (none), 1 (mild), 2 (moderate), or 3 (severe).			
Units: points on a scale			
arithmetic mean	6.4	6.7	-
standard deviation	± 1.16	± 1.25	-
Other - Morning (AM) pre-dose instantaneous (i) TNSS			
Total Symptom Scores (scale of 0-9; sum of the three individual nasal or ocular scores) based on 3 nasal symptoms (rhinorrhea, nasal congestion, and post-nasal drip) and 3 ocular symptoms (eye itching/burning, eye tearing/watering, and eye redness). Symptoms were evaluated on a scale of 0 (none), 1 (mild), 2 (moderate), or 3 (severe).			
Units: points on a scale			
arithmetic mean	6.3	6.5	-
standard deviation	± 1.5	± 1.57	-
Other - AM Reflective TNSS			
Total Symptom Scores (scale of 0-9; sum of the three individual nasal or ocular scores) based on 3 nasal symptoms (rhinorrhea, nasal congestion, and post-nasal drip) and 3 ocular symptoms (eye itching/burning, eye tearing/watering, and eye redness). Symptoms were evaluated on a scale of 0 (none), 1 (mild), 2 (moderate), or 3 (severe).			

Units: points on a scale arithmetic mean standard deviation	6.4 ± 1.24	6.7 ± 1.36	-
Other - Evening (PM) Reflective TNSS			
Total Symptom Scores (scale of 0-9; sum of the three individual nasal or ocular scores) based on 3 nasal symptoms (rhinorrhea, nasal congestion, and post-nasal drip) and 3 ocular symptoms (eye itching/burning, eye tearing/watering, and eye redness). Symptoms were evaluated on a scale of 0 (none), 1 (mild), 2 (moderate), or 3 (severe).			
Units: points on a scale arithmetic mean standard deviation	6.3 ± 1.31	6.7 ± 1.32	-
Other - Daily Reflective TOSS			
Total Symptom Scores (scale of 0-9; sum of the three individual nasal or ocular scores) based on 3 nasal symptoms (rhinorrhea, nasal congestion, and post-nasal drip) and 3 ocular symptoms (eye itching/burning, eye tearing/watering, and eye redness). Symptoms were evaluated on a scale of 0 (none), 1 (mild), 2 (moderate), or 3 (severe).			
Units: points on a scale arithmetic mean standard deviation	2.4 ± 2.17	3.1 ± 2.27	-
Other - AM pre-dose iTOSS			
Total Symptom Scores (scale of 0-9; sum of the three individual nasal or ocular scores) based on 3 nasal symptoms (rhinorrhea, nasal congestion, and post-nasal drip) and 3 ocular symptoms (eye itching/burning, eye tearing/watering, and eye redness). Symptoms were evaluated on a scale of 0 (none), 1 (mild), 2 (moderate), or 3 (severe).			
Units: points on a scale arithmetic mean standard deviation	2.4 ± 2.24	3.1 ± 2.17	-
Other - AM Reflective TOSS			
Total Symptom Scores (scale of 0-9; sum of the three individual nasal or ocular scores) based on 3 nasal symptoms (rhinorrhea, nasal congestion, and post-nasal drip) and 3 ocular symptoms (eye itching/burning, eye tearing/watering, and eye redness). Symptoms were evaluated on a scale of 0 (none), 1 (mild), 2 (moderate), or 3 (severe).			
Units: points on a scale arithmetic mean standard deviation	2.4 ± 2.2	3 ± 2.16	-
Other - PM Reflective TOSS			
Total Symptom Scores (scale of 0-9; sum of the three individual nasal or ocular scores) based on 3 nasal symptoms (rhinorrhea, nasal congestion, and post-nasal drip) and 3 ocular symptoms (eye itching/burning, eye tearing/watering, and eye redness). Symptoms were evaluated on a scale of 0 (none), 1 (mild), 2 (moderate), or 3 (severe).			
Units: points on a scale arithmetic mean standard deviation	2.4 ± 2.19	3.2 ± 2.42	-

## End points

### End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Vehicle placebo nasal spray once daily	
Reporting group title	FFNS 110 mcg
Reporting group description:	
Fluticasone Furoate Nasal Spray (FFNS) 110 micrograms (mcg) once daily	

### Primary: Mean change from baseline in daily rTNSS over the entire treatment period (28 days)

End point title	Mean change from baseline in daily rTNSS over the entire treatment period (28 days)
End point description:	The Total Nasal Symptom Score (TNSS) is the sum (scale 0-9) of the individual nasal scores for rhinorrhea, nasal congestion, and post-nasal drip. All symptoms were evaluated using a scale of 0 (None), 1 (Mild), 2 (Moderate), or 3 (Severe). Reflective (r) assessments were performed in the morning (AM) and evening (PM) and assessed the participant's symptoms over the preceding 12 hours. The daily reflective Total Nasal Symptoms Score (daily rTNSS) is the average of the AM and PM rTNSS. Mean change from baseline was calculated as the participant's treatment period mean minus the baseline mean. Intent-to-Treat (ITT) Population: all participants who received at least one dose of study medication
End point type	Primary
End point timeframe:	
Baseline through Week 4 (28 days)	

End point values	Placebo	FFNS 110 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49 <sup>[1]</sup>	53		
Units: points on a scale				
least squares mean (standard error)	-2.1 (± 0.25)	-2.17 (± 0.23)		

Notes:

[1] - ITT population

### Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Center, baseline eosinophils, baseline symptom score, age, and gender were included as covariates in all efficacy analyses.	
Comparison groups	FFNS 110 mcg v Placebo

Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.845
Method	ANCOVA

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**Secondary: Mean change from baseline in AM rTNSS, PM rTNSS, and AM pre-dose iTNSS over the entire treatment period (28 days)**

End point title	Mean change from baseline in AM rTNSS, PM rTNSS, and AM pre-dose iTNSS over the entire treatment period (28 days)
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End point description:

The TNSS is the Total Nasal Symptom Score (scale 0-9), a sum of the individual nasal scores for (1) rhinorrhea, (2) nasal congestion, and (3) post-nasal drip. All 3 symptoms were evaluated using a scale of: 0 (None), 1 (Mild), 2 (Moderate), or 3 (Severe). Reflective (r) assessments were performed in the morning (AM) and evening (PM) and assessed the participant's symptoms over the preceding 12 hours (AM rTNSS, PM rTNSS). The AM pre-dose instantaneous assessment (AM pre-dose iTNSS) was performed in the morning just prior to dosing and assessed symptoms at that moment.

End point type	Secondary
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End point timeframe:

Baseline through Week 4 (28 days)

End point values	Placebo	FFNS 110 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49 <sup>[2]</sup>	53		
Units: points on a scale				
least squares mean (standard error)				
AM pre-dose iTNSS	-1.82 (± 0.26)	-1.9 (± 0.24)		
AM rTNSS	-2.13 (± 0.27)	-2.15 (± 0.24)		
PM rTNSS	-2.09 (± 0.25)	-2.19 (± 0.23)		

Notes:

[2] - ITT population

**Statistical analyses**

No statistical analyses for this end point

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**Secondary: Mean change from baseline in daily reflective individual nasal symptoms score over the entire treatment period (28 days)**

End point title	Mean change from baseline in daily reflective individual nasal symptoms score over the entire treatment period (28 days)
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End point description:

Mean change for the individual symptoms of rhinorrhea, nasal congestion, and post-nasal drip. Reflective rating represents the participant's symptoms over the preceding 12 hours. Reflective assessments were performed in the morning (AM) and evening (PM). The daily reflective individual nasal symptom score average of the AM and PM reflective individual nasal symptoms is the daily reflective individual nasal symptom score. All symptoms were evaluated on a 0 (none) to 3 (severe) scale.

End point type	Secondary
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End point timeframe:

Baseline through Week 4 (28 days)

<b>End point values</b>	Placebo	FFNS 110 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49 <sup>[3]</sup>	53		
Units: points on a scale				
least squares mean (standard error)				
Rhinorrhea	-0.64 (± 0.09)	-0.72 (± 0.08)		
Nasal congestion	-0.75 (± 0.09)	-0.79 (± 0.08)		
Post-nasal drip	-0.7 (± 0.1)	-0.67 (± 0.09)		

Notes:

[3] - ITT population

### Statistical analyses

No statistical analyses for this end point

### Secondary: Mean change from baseline in AM pre-dose instantaneous individual nasal symptoms over the entire treatment period (28 days)

End point title	Mean change from baseline in AM pre-dose instantaneous individual nasal symptoms over the entire treatment period (28 days)
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End point description:

The AM pre-dose instantaneous assessment is performed in the morning prior to dosing and evaluates symptoms at that moment. The individual symptoms of rhinorrhea, nasal congestion, and post-nasal drip were measured at this time. All three symptoms were evaluated using a 0 (none) to 3 (severe) scale. This assessment provides information on the duration of action of the treatment.

End point type	Secondary
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End point timeframe:

Baseline through Week 4 (28 days)

<b>End point values</b>	Placebo	FFNS 110 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49 <sup>[4]</sup>	53		
Units: points on a scale				
least squares mean (standard error)				
Rhinorrhea	-0.52 (± 0.09)	-0.61 (± 0.09)		
Nasal congestion	-0.64 (± 0.09)	-0.71 (± 0.08)		
Post-nasal drip	-0.66 (± 0.1)	-0.58 (± 0.09)		

Notes:

[4] - ITT population

### Statistical analyses

No statistical analyses for this end point

### Secondary: Mean change from baseline in AM and PM reflective individual nasal

**symptoms over the entire treatment period (28 days)**

End point title	Mean change from baseline in AM and PM reflective individual nasal symptoms over the entire treatment period (28 days)
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End point description:

Mean change for the individual symptoms of rhinorrhea, nasal congestion, and post-nasal drip as measured in the morning and evening. Reflective rating represents the participant's symptoms over the preceding 12 hours. All symptoms were evaluated on a 0 (none) to 3 (severe) scale.

End point type	Secondary
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End point timeframe:

Baseline through Week 4 (28 days)

End point values	Placebo	FFNS 110 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49 <sup>[5]</sup>	53		
Units: points on a scale				
least squares mean (standard error)				
AM, rhinorrhea	-0.65 (± 0.09)	-0.72 (± 0.08)		
PM, rhinorrhea	-0.63 (± 0.09)	-0.72 (± 0.09)		
AM, nasal congestion	-0.75 (± 0.09)	-0.78 (± 0.08)		
PM, nasal congestion	-0.76 (± 0.09)	-0.79 (± 0.09)		
AM, post-nasal drip	-0.73 (± 0.1)	-0.65 (± 0.09)		
PM, post-nasal drip	-0.69 (± 0.1)	-0.68 (± 0.09)		

Notes:

[5] - ITT population

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Mean change from baseline in total ocular symptoms over the entire treatment period (28 days)**

End point title	Mean change from baseline in total ocular symptoms over the entire treatment period (28 days)
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End point description:

The Total Ocular Symptom Score (TOSS) is a sum (scale 0-9) of the individual ocular scores for eye itching/burning, eye tearing/watering, and eye redness. All 3 symptoms were evaluated using a scale of 0 (None), 1 (Mild), 2 (Moderate), or 2 (Severe). The daily reflective TOSS (daily rTOSS) is the average of the morning (AM) and evening (PM) rTOSS assessments that measure symptoms over the previous 12 hours. The AM pre-dose instantaneous (iTOSS) assessment is performed in the morning prior to dosing and evaluates symptoms at that moment, providing data on the duration of action of treatment.

End point type	Secondary
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End point timeframe:

Baseline through Week 4 (28 days)

<b>End point values</b>	Placebo	FFNS 110 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49 <sup>[6]</sup>	53		
Units: points on a scale				
least squares mean (standard error)				
Daily rTOSS	-0.77 (± 0.16)	-1.04 (± 0.14)		
AM pre-dose iTOSS	-0.85 (± 0.17)	-0.98 (± 0.15)		
AM rTOSS	-0.81 (± 0.17)	-0.96 (± 0.16)		
PM rTOSS	-0.74 (± 0.16)	-1.13 (± 0.15)		

Notes:

[6] - ITT population

### Statistical analyses

No statistical analyses for this end point

### Secondary: Mean change from baseline in daily reflective individual ocular symptoms over the entire treatment period (28 days)

End point title	Mean change from baseline in daily reflective individual ocular symptoms over the entire treatment period (28 days)
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End point description:

Mean change for the individual symptoms of eye itching/burning, eye tearing/watering, and eye redness. Reflective rating represents the participant's symptoms over the preceding 12 hours. Reflective assessments were performed twice daily (AM and PM). The average of the AM and PM reflective individual ocular symptoms is the daily reflective individual ocular symptoms. Reflective individual ocular symptoms were evaluated on a 0 (none) to 3 (severe) scale.

End point type	Secondary
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End point timeframe:

Baseline through Week 4 (28 days)

<b>End point values</b>	Placebo	FFNS 110 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49 <sup>[7]</sup>	53		
Units: points on a scale				
least squares mean (standard error)				
Eye itching/burning	-0.32 (± 0.07)	-0.45 (± 0.06)		
Eye tearing/watering	-0.29 (± 0.06)	-0.31 (± 0.06)		
Eye redness	-0.17 (± 0.06)	-0.28 (± 0.05)		

Notes:

[7] - ITT population

### Statistical analyses

No statistical analyses for this end point

### Secondary: Mean change from baseline in AM pre-dose instantaneous individual ocular symptoms over the entire treatment period (28 days)

End point title	Mean change from baseline in AM pre-dose instantaneous individual ocular symptoms over the entire treatment period
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(28 days)

End point description:

The AM pre-dose instantaneous assessment is performed in the morning prior to dosing and evaluates symptoms at that moment. The individual symptoms of eye itching/burning, eye tearing/watering, and eye redness were measured at this time. All three symptoms were evaluated using a 0 (none) to 3 (severe) scale. This assessment provides information on the duration of action of the treatment.

End point type Secondary

End point timeframe:

Baseline through Week 4 (28 days)

End point values	Placebo	FFNS 110 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49 <sup>[8]</sup>	53		
Units: points on a scale				
least squares mean (standard error)				
Eye itching/burning	-0.35 (± 0.08)	-0.37 (± 0.07)		
Eye tearing/watering	-0.3 (± 0.06)	-0.33 (± 0.06)		
Eye redness	-0.21 (± 0.05)	-0.27 (± 0.05)		

Notes:

[8] - ITT population

### Statistical analyses

No statistical analyses for this end point

### Secondary: Mean change from baseline in AM and PM reflective individual ocular symptoms over the entire treatment period (28 days)

End point title Mean change from baseline in AM and PM reflective individual ocular symptoms over the entire treatment period (28 days)

End point description:

Mean change for the individual symptoms of eye itching/burning, eye tearing/watering, and eye redness. Reflective ratings assessed the participant's symptoms over the preceding 12 hours. Reflective assessments were performed twice daily (AM and PM) and were evaluated on a 0 (none) to 3 (severe) scale.

End point type Secondary

End point timeframe:

Baseline through Week 4 (28 days)

End point values	Placebo	FFNS 110 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49 <sup>[9]</sup>	53		
Units: points on a scale				
least squares mean (standard error)				
AM, eye itching/burning	-0.34 (± 0.07)	-0.42 (± 0.06)		
PM, eye itching/burning	-0.3 (± 0.07)	-0.48 (± 0.06)		
AM, eye tearing/watering	-0.32 (± 0.07)	-0.29 (± 0.06)		
PM, eye tearing/watering	-0.27 (± 0.06)	-0.33 (± 0.05)		

AM, eye redness	-0.16 (± 0.06)	-0.23 (± 0.05)		
PM, eye redness	-0.19 (± 0.06)	-0.31 (± 0.05)		

Notes:

[9] - ITT population

### **Statistical analyses**

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs) and non-serious AEs were collected from Visit 2 (the start of study medication) to 5 days after the follow-up Visit 6 (approximately 34 days).

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	12.0

### Reporting groups

Reporting group title	FFNS 110 mcg
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Reporting group description:

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

Reporting group title	Placebo
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Reporting group description:

Vehicle placebo nasal spray once daily

<b>Serious adverse events</b>	FFNS 110 mcg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Respiratory, thoracic and mediastinal disorders			
Upper respiratory tract infection			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 3 %

<b>Non-serious adverse events</b>	FFNS 110 mcg	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 53 (16.98%)	3 / 49 (6.12%)	
Nervous system disorders			
Migraine			
subjects affected / exposed	2 / 53 (3.77%)	1 / 49 (2.04%)	
occurrences (all)	2	2	
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	3 / 53 (5.66%)	1 / 49 (2.04%)	
occurrences (all)	4	3	
Nasal ulcer			
subjects affected / exposed	2 / 53 (3.77%)	1 / 49 (2.04%)	
occurrences (all)	3	1	
Epistaxis			
subjects affected / exposed	2 / 53 (3.77%)	0 / 49 (0.00%)	
occurrences (all)	2	0	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 October 2007	The protocol amendment, made prior to beginning study enrolment, was to correct the wording regarding randomization stratification. Wording was changed to reflect that randomization would be stratified by baseline eosinophil levels collected by the nasal cytology assessment (positive level of $\geq 5\%$ versus negative levels of $< 5\%$ ). This change applied to all study centers.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported