Clinical trial results:
A randomized, double-blind, placebo controlled, parallel group, multi-centre, 2-week treatment study to evaluate the safety and efficacy of fluticasone furoate nasal spray (FFNS) 110 mcg, administered either once daily or twice daily, compared with placebo, as effective monotherapy in the treatment of uncomplicated acute rhinosinusitis (ARS) in adult and adolescent subjects 12 years of age and older.

Summary

EudraCT number	2009-015014-22
Trial protocol	EE NL NO SE ES DE PL CZ BG
Global end of trial date	16 July 2010

Results information

Result version number	v1 (current)
This version publication date	27 April 2016
First version publication date	03 May 2015

Trial information

Trial identification

Sponsor protocol code	FFS113203

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01018030
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, GSK Response Center, 1 866-435-7343,
Scientific contact	GSK Response Center, GSK Response Center, 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	09 September 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 July 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to evaluate the safety and efficacy of two doses of FFNS (110 mcg once daily and 110 mcg twice daily) compared to placebo as monotherapy in the treatment of adult and adolescent subjects 12 years of age and older with uncomplicated ARS.

Protection of trial subjects:

Safety monitoring included monitoring for adverse events, clinical laboratory tests, vital signs, and nasal examinations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 January 2010
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	Netherlands: 40
Country: Number of subjects enrolled	Norway: 24
Country: Number of subjects enrolled	Poland: 58
Country: Number of subjects enrolled	Spain: 24
Country: Number of subjects enrolled	Sweden: 34
Country: Number of subjects enrolled	Bulgaria: 104
Country: Number of subjects enrolled	Czech Republic: 26
Country: Number of subjects enrolled	Estonia: 39
Country: Number of subjects enrolled	Germany: 157
Country: Number of subjects enrolled	Canada: 123
Country: Number of subjects enrolled	Russian Federation: 55
Country: Number of subjects enrolled	Ukraine: 53
Worldwide total number of subjects	737
EEA total number of subjects	506

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)	43
Adults (18-64 years)	653
From 65 to 84 years	41
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were randomized to a double-blind, placebo-controlled, parallel-group, 2-week treatment study to evaluate the safety and efficacy of fluticasone furoate nasal spray 110 micrograms (either once or twice daily) for the treatment of uncomplicated acute rhinosinusitis in adults and adolescent participants 12 years of age and older.

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, Monitor, Carer, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Vehicle Placebo Nasal Spray administered twice daily (BD) for 14 days

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

Dosage and administration details:

vehicle placebo

Arm title	FFNS 110 mcg QD

Arm description:

Fluticasone Furoate Nasal Spray (FFNS) 110 micrograms (mcg) administered once daily (QD) in the morning and vehicle placebo nasal spray administered in the evening for 14 days

Arm type	Experimental
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

110 micrograms once daily

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

Dosage and administration details:

vehicle placebo

Arm title	FFNS 110 mcg BD

Arm description:	
FFNS 110 mcg administered BD for 14 days	
Arm type	Experimental
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

110 micrograms twice daily

Number of subjects in period 1	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD
Started	245	240	252
Completed	227	232	239
Not completed	18	8	13
Consent withdrawn by subject	2	2	4
Physician decision	1	-	1
Adverse event, non-fatal	10	5	5
Lost to follow-up	2	-	3
Protocol deviation	2	1	-
Lack of efficacy	1	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Vehicle Placebo Nasal Spray administered twice daily (BD) for 14 days	
Reporting group title	FFNS 110 mcg QD
Reporting group description:	
Fluticasone Furoate Nasal Spray (FFNS) 110 micrograms (mcg) administered once daily (QD) in the morning and vehicle placebo nasal spray administered in the evening for 14 days	
Reporting group title	FFNS 110 mcg BD
Reporting group description:	
FFNS 110 mcg administered BD for 14 days	

Reporting group values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD
Number of subjects	245	240	252
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	39.1	39.7	39
standard deviation	± 14.81	± 15.64	± 16.02
Gender categorical			
Units: Subjects			
Female	143	148	169
Male	102	92	83
Race, Customized			
Units: Subjects			
White	238	234	244
Black	3	0	3
Other (Other than White and Black)	4	6	5

Reporting group values	Total		
Number of subjects	737		
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	460		
Male	277		

Race, Customized Units: Subjects			
White	716		
Black	6		
Other (Other than White and Black)	15		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Vehicle Placebo Nasal Spray administered twice daily (BD) for 14 days	
Reporting group title	FFNS 110 mcg QD
Reporting group description:	
Fluticasone Furoate Nasal Spray (FFNS) 110 micrograms (mcg) administered once daily (QD) in the morning and vehicle placebo nasal spray administered in the evening for 14 days	
Reporting group title	FFNS 110 mcg BD
Reporting group description:	
FFNS 110 mcg administered BD for 14 days	

Primary: Mean Change From Baseline in the Daily Major Symptom Score (MSS) Over the Entire Treatment Period (Weeks 1-2)

End point title	Mean Change From Baseline in the Daily Major Symptom Score (MSS) Over the Entire Treatment Period (Weeks 1-2)
End point description:	
The MSS was calculated as the sum of 3 individual symptom scores for nasal congestion/stuffiness, sinus headache/pressure or facial pain/pressure, and postnasal drip. Daily MSS was calculated as the average of the morning (AM) and evening (PM) MSS. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. The total score ranged from 0 to 9. Change from baseline was calculated as the daily MSS averaged over the entire treatment period minus daily MSS over the baseline period (defined as the average daily MSS over the last 3 days prior to randomization). Intent-to-Treat (ITT) Population: all randomized participants who received at least one dose of ouble-blind study drug. Participants with missing diary data at baseline or post-baseline were not included in this analysis.	
End point type	Primary
End point timeframe:	
Baseline and entire treatment period (up to 2 weeks)	

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	242[1]	237[2]	245[3]	
Units: units on a scale				
least squares mean (standard error)	-2.97 (± 0.12)	-3.36 (± 0.13)	-3.33 (± 0.13)	

Notes:

[1] - ITT Population.

[2] - ITT Population.

[3] - ITT Population.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
The estimation for least squares mean was adjusted for baseline value, country, allergic rhinitis status, age, and gender.	
Comparison groups	Placebo v FFNS 110 mcg QD v FFNS 110 mcg BD

Number of subjects included in analysis	724
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.386
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.67
upper limit	-0.1

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

The estimation for least squares mean was adjusted for baseline value, country, allergic rhinitis status, age, and gender.

Comparison groups	Placebo v FFNS 110 mcg BD v FFNS 110 mcg QD
Number of subjects included in analysis	724
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.014
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.357
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.64
upper limit	-0.07

Secondary: First Time to Symptom Improvement

End point title	First Time to Symptom Improvement

End point description:

Symptom improvement was defined as symptom scores less than or equal to 1 (i.e., mild or no symptoms) for all three major symptoms (nasal congestion/stuffiness, sinus headache/pressure or facial pain/pressure, and postnasal drip) on 2 consecutive 12-hour assessments. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. Participants with missing diary data at baseline or post-baseline were not included in this analysis.

End point type	Secondary

End point timeframe:

Entire treatment period (up to 2 weeks)

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	243[4]	239[5]	247[6]	
Units: days				
median (full range (min-max))	8 (1 to 14)	7 (1 to 14)	7 (1 to 14)	

Notes:

[4] - ITT Population.

[5] - ITT Population.

[6] - ITT Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline Over the Entire Treatment Period in AM MSS

End point title	Mean Change From Baseline Over the Entire Treatment Period in AM MSS

End point description:

Mean change from baseline in MSS for nasal congestion/stuffiness, sinus headache/pressure or facial pain/pressure, and postnasal drip as measured in the morning (AM) was calculated as the Week 1-2 value minus the baseline value. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. The total score ranged from 0 to 9. Change from baseline in AM MSS was calculated as the AM MSS averaged over the entire treatment period minus the AM MSS over the baseline period (defined as the average AM MSS over the last 3 days prior to randomization). Participants with missing diary data at baseline or post-baseline were not included in this analysis.

End point type	Secondary

End point timeframe:

Baseline and entire treatment period (up to 2 weeks)

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	241[7]	235[8]	244[9]	
Units: units on a scale				
arithmetic mean (standard deviation)	-3.1 (± 0.12)	-3.4 (± 0.12)	-3.3 (± 0.11)	

Notes:

[7] - ITT Population

[8] - ITT Population

[9] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline Over the Entire Treatment Period in PM MSS

End point title	Mean Change From Baseline Over the Entire Treatment Period in PM MSS

End point description:

Mean change from baseline in MSS for nasal congestion/stuffiness, sinus headache/pressure or facial pain/pressure, and postnasal drip as measured in the evening (PM) was calculated as the Week 1-2 value minus the baseline value. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. The total score ranged from 0 to 9. Change from baseline in PM MSS

was calculated as the PM MSS averaged over the entire treatment period minus the PM MSS over the baseline period (defined as the average PM MSS over the last 3 days prior to randomization). Participants with missing diary data at baseline or post-baseline were not included in this analysis.

End point type	Secondary

End point timeframe:

Baseline and entire treatment period (up to 2 weeks)

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	242[10]	236[11]	242[12]	
Units: units on a scale				
arithmetic mean (standard error)	-3 (± 0.12)	-3.4 (± 0.12)	-3.4 (± 0.12)	

Notes:

[10] - ITT Population.

[11] - ITT Population.

[12] - ITT Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline Over the Entire Treatment Period in the Daily Nasal Congestion/Stuffiness Score

End point title	Mean Change From Baseline Over the Entire Treatment Period in the Daily Nasal Congestion/Stuffiness Score

End point description:

Mean change from baseline was calculated as the Week 1-2 value minus the baseline value. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. The score ranged from 0 to 3. Change from baseline in the daily nasal congestion/stuffiness score was calculated as the daily score averaged over the entire treatment period minus the daily score over the baseline period (defined as the average daily score over the last 3 days prior to randomization). Participants with missing diary data at baseline or post-baseline were not included in this analysis.

End point type	Secondary

End point timeframe:

Baseline and entire treatment period (up to 2 weeks)

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	242[13]	237[14]	245[15]	
Units: units on a scale				
arithmetic mean (standard error)	-1 (± 0.04)	-1.1 (± 0.04)	-1.1 (± 0.04)	

Notes:

[13] - ITT Population.

[14] - ITT Population.

[15] - ITT Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline Over the Entire Treatment Period in the AM Nasal Congestion/Stuffiness Score

End point title	Mean Change From Baseline Over the Entire Treatment Period in the AM Nasal Congestion/Stuffiness Score

End point description:

Mean change from baseline was calculated as the Week 1-2 value minus the baseline value. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. The score ranged from 0 to 3. Change from baseline in the AM nasal congestion/stuffiness score was calculated as the AM score averaged over the entire treatment period minus the AM score over the baseline period (defined as the average AM score over the last 3 days prior to randomization). Participants with missing diary data at baseline or post-baseline were not included in this analysis.

End point type	Secondary

End point timeframe:

Baseline and entire treatment period (up to 2 weeks)

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	241[16]	235[17]	244[18]	
Units: units on a scale				
arithmetic mean (standard error)	-1 (± 0.04)	-1.1 (± 0.04)	-1.1 (± 0.04)	

Notes:

[16] - ITT Population

[17] - ITT Population

[18] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline Over the Entire Treatment Period in the PM Nasal Congestion/Stuffiness Score

End point title	Mean Change From Baseline Over the Entire Treatment Period in the PM Nasal Congestion/Stuffiness Score

End point description:

Mean change from baseline was calculated as the Week 1-2 value minus the baseline value. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. The score ranged from 0 to 3. Change from baseline in the PM nasal congestion/stuffiness score was calculated as the PM score averaged over the entire treatment period minus the PM score over the baseline period (defined as the average PM score over the last 3 days prior to randomization). Participants with missing diary data at baseline or post-baseline were not included in this analysis.

End point type	Secondary

End point timeframe:

Baseline and entire treatment period (up to 2 weeks)

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	242[19]	237[20]	242[21]	
Units: units on a scale				
arithmetic mean (standard error)	-1 (± 0.04)	-1.1 (± 0.05)	-1.1 (± 0.04)	

Notes:

[19] - ITT Population.

[20] - ITT Population.

[21] - ITT Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline Over the Entire Treatment Period in the Daily Sinus Headache/Pressure or Facial Pain/Pressure Score

End point title	Mean Change From Baseline Over the Entire Treatment Period in the Daily Sinus Headache/Pressure or Facial Pain/Pressure Score

End point description:

Mean change from baseline was calculated as the Week 1-2 value minus the baseline value. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. The score ranged from 0 to 3. Change from baseline in the daily sinus headache/pressure or facial pain/pressure score was calculated as the daily score averaged over the entire treatment period minus the daily score over the baseline period (defined as the average daily score over the last 3 days prior to randomization). Participants with missing diary data at baseline or post-baseline were not included in this analysis.

End point type	Secondary

End point timeframe:

Baseline and entire treatment period (up to 2 weeks)

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	242[22]	237[23]	245[24]	
Units: units on a scale				
arithmetic mean (standard error)	-1.1 (± 0.04)	-1.2 (± 0.05)	-1.2 (± 0.05)	

Notes:

[22] - ITT Population.

[23] - ITT Population.

[24] - ITT Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline Over the Entire Treatment Period in the AM Sinus Headache/Pressure or Facial Pain/Pressure Score

End point title	Mean Change From Baseline Over the Entire Treatment Period in the AM Sinus Headache/Pressure or Facial Pain/Pressure Score

End point description:

Mean change from baseline was calculated as the Week 1-2 value minus the baseline value. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. The score ranged from 0 to 3. Change from baseline in the AM sinus headache/pressure or facial pain/pressure score was calculated as the AM score averaged over the entire treatment period minus the AM score over the baseline period (defined as the average AM score over the last 3 days prior to randomization). Participants with missing diary data at baseline or post-baseline were not included in this analysis.

End point type	Secondary

End point timeframe:

Baseline and entire treatment period (up to 2 weeks)

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	241[25]	235[26]	244[27]	
Units: units on a scale				
arithmetic mean (standard error)	-1.2 (± 0.05)	-1.2 (± 0.05)	-1.2 (± 0.05)	

Notes:

[25] - ITT Population.

[26] - ITT Population.

[27] - ITT Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline Over the Entire Treatment Period in the PM Sinus Headache/Pressure or Facial Pain/Pressure Score

End point title	Mean Change From Baseline Over the Entire Treatment Period in the PM Sinus Headache/Pressure or Facial Pain/Pressure Score

End point description:

Mean change from baseline was calculated as the Week 1-2 value minus the baseline value. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. The score ranged from 0 to 3. Change from baseline in the PM sinus headache/pressure or facial pain/pressure score was calculated as the PM score averaged over the entire treatment period minus the PM score over the baseline period (defined as the average PM score over the last 3 days prior to randomization). Participants with missing diary data at baseline or post-baseline were not included in this analysis.

End point type	Secondary

End point timeframe:

Baseline and entire treatment period (up to 2 weeks)

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	242[28]	237[29]	242[30]	
Units: units on a scale				
arithmetic mean (standard error)	-1.1 (± 0.05)	-1.2 (± 0.05)	-1.2 (± 0.05)	

Notes:

[28] - ITT Population

[29] - ITT Population

[30] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline Over the Entire Treatment Period in the Daily Postnasal Drip Score

End point title	Mean Change From Baseline Over the Entire Treatment Period in the Daily Postnasal Drip Score

End point description:

Mean change from baseline was calculated as the Week 1-2 value minus the baseline value. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. The score ranged from 0 to 3. Change from baseline in the daily postnasal drip score was calculated as the daily postnasal drip score averaged over the entire treatment period minus the daily postnasal drip score over the baseline period (defined as the average daily postnasal drip score over the last 3 days prior to randomization). Participants with missing diary data at baseline or post-baseline were not included in this analysis.

End point type	Secondary

End point timeframe:

Baseline and entire treatment period (up to 2 weeks)

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	242[31]	237[32]	245[33]	
Units: units on a scale				
arithmetic mean (standard error)	-0.9 (± 0.05)	-1 (± 0.05)	-1 (± 0.04)	

Notes:

[31] - ITT Population

[32] - ITT Population

[33] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline Over the Entire Treatment Period in the AM Postnasal Drip Score

End point title	Mean Change From Baseline Over the Entire Treatment Period in the AM Postnasal Drip Score

End point description:

Mean change from baseline was calculated as the Week 1-2 value minus the baseline value. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. The score ranged from 0 to 3. Change from baseline in the AM postnasal drip score was calculated as the AM postnasal drip score averaged over the entire treatment period minus the AM postnasal drip score over the baseline period (defined as the average AM postnasal drip score over the last 3 days prior to randomization). Participants with missing diary data at baseline or post-baseline were not included in this analysis.

End point type	Secondary

End point timeframe:

Baseline and entire treatment period (up to 2 weeks)

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	241[34]	235[35]	244[36]	
Units: units on a scale				
arithmetic mean (standard error)	-0.9 (± 0.05)	-1.1 (± 0.05)	-1 (± 0.04)	

Notes:

[34] - ITT Population

[35] - ITT Population

[36] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline Over the Entire Treatment Period in the PM Postnasal Drip Score

End point title	Mean Change From Baseline Over the Entire Treatment Period in the PM Postnasal Drip Score

End point description:

Mean change from baseline was calculated as the Week 1-2 value minus the baseline value. Each individual symptom was scored on a scale of 0 to 3: 0=none; 1=mild; 2=moderate; 3=severe. The score ranged from 0 to 3. Change from baseline in the PM postnasal drip score was calculated as the PM postnasal drip score averaged over the entire treatment period minus the PM postnasal drip score over the baseline period (defined as the average PM postnasal drip score over the last 3 days prior to randomization). Participants with missing diary data at baseline or post-baseline were not included in this analysis.

End point type	Secondary

End point timeframe:

Baseline and entire treatment period (up to 2 weeks)

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	242[37]	236[38]	242[39]	
Units: units on a scale				
arithmetic mean (standard error)	-0.9 (± 0.05)	-1.1 (± 0.05)	-1 (± 0.05)	

Notes:

[37] - ITT Population

[38] - ITT Population

[39] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Who Require the Use of an Antibiotic Due to the Development of Fulminant Bacterial Rhinosinusitis (FBRS)

End point title	Number of Participants Who Require the Use of an Antibiotic Due to the Development of Fulminant Bacterial Rhinosinusitis (FBRS)

End point description:

Participants who required the use of an antibiotic due to the development of FBRS during the 2-week treatment period and the 2-week follow-up period were included in the analysis.

End point type	Secondary

End point timeframe:

4 weeks

End point values	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	245[40]	240[41]	252[42]	
Units: participants				
number (not applicable)	7	7	7	

Notes:

[40] - ITT Population

[41] - ITT Population

[42] - ITT Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Adverse events were reported from randomization until the follow up contact (Day 29).	
Adverse event reporting additional description:	
The MedDRA version used for this study was not available.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Vehicle Placebo Nasal Spray administered twice daily (BD) for 14 days	
Reporting group title	FFNS 110 mcg QD
Reporting group description:	
Fluticasone Furoate Nasal Spray (FFNS) 110 micrograms (mcg) administered once daily (QD) in the morning and vehicle placebo nasal spray administered in the evening for 14 days	
Reporting group title	FFNS 110 mcg BD
Reporting group description:	
FFNS 110 mcg administered BD for 14 days	

Serious adverse events	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 245 (0.00%)	0 / 240 (0.00%)	1 / 252 (0.40%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	0 / 245 (0.00%)	0 / 240 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Placebo	FFNS 110 mcg QD	FFNS 110 mcg BD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 245 (8.57%)	23 / 240 (9.58%)	23 / 252 (9.13%)
Nervous system disorders			

Headache			
subjects affected / exposed	9 / 245 (3.67%)	9 / 240 (3.75%)	14 / 252 (5.56%)
occurrences (all)	10	9	16
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	5 / 245 (2.04%)	11 / 240 (4.58%)	3 / 252 (1.19%)
occurrences (all)	5	12	4
Infections and infestations			
Sinusitis bacterial			
subjects affected / exposed	8 / 245 (3.27%)	7 / 240 (2.92%)	7 / 252 (2.78%)
occurrences (all)	8	7	7

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 February 2010	This is a country-specific amendment. The purpose of FFS113203 Amendment 01 is to remove the inclusion of adolescent subjects (12 ages < 18) for Czech Republic. Inclusion criterion 3., Age, on page 19 of the original protocol is amended accordingly.
26 February 2010	This is a country-specific amendment. The purpose of FFS113203 Amendment 02 is to clarify that anterior rhinoscopy using a speculum is used to assess nasal cavities during nasal examination.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported