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Study No.: FFR111158
Title: A Pilot, Randomised, Double-blind, Placebo-controlled, Parallel-group, Multi-centre 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
Rationale: Non-allergic rhinitis (NAR) is a common disease affecting about 17 million people in the US [Settipane, 2001]. One sub-class of NAR, irritant rhinitis, can be caused by a variety of irritant triggers which include environmental factors, such as physical and/or chemical compounds in the air, which produce nasal congestion, rhinorrhea and postnasal drip. Intranasal corticosteroids (INS) are the most effective anti-inflammatory agent for similar symptoms seen in allergic rhinitis through their inhibitory effects on inflammatory cells and mediator activity. This study was performed in order to assess the effects of fluticasone furoate, an INS, on an irritant (non-allergic) form of this disease caused by air pollution.
Phase: IIa
Study Period: 09Mar2008 - 10Feb2009
Study Design: Randomized, double-blind, placebo-controlled, parallel-group, multicenter study
Centres: 7 centers in Bangkok, Thailand
Indication: Irritant (non-allergic) rhinitis
Treatments: Fluticasone furoate nasal spray (FFNS) 110 mcg once daily, vehicle placebo nasal spray once daily
Objectives: To compare the efficacy and safety of fluticasone furoate nasal spray 110 mcg (FFNS) once daily with placebo nasal spray in subjects with irritant (non-allergic) rhinitis triggered predominantly by air pollution
Primary Outcome/Efficacy Variable: Mean change from baseline over the entire treatment period in daily reflective total nasal symptom scores (daily rTNSS)
Secondary Outcome/Efficacy Variable(s): Nasal Symptoms Mean change from baseline over the entire treatment period in morning (AM) pre-dose instantaneous total nasal symptom scores (AM predose iTNSS) Mean change from baseline over the entire treatment period in AM rTNSS Mean change from baseline over the entire treatment period in evening (PM) rTNSS Mean change from baseline over the entire treatment period in individual (1) daily reflective, (2) AM pre-dose instantaneous, (3) AM reflective, and (4) PM reflective nasal symptom scores for rhinorrhea, nasal congestion, and postnasal drip. Ocular Symptoms Mean change from baseline over the entire treatment period in the daily, reflective, total ocular symptom score (rTOSS). Mean change from baseline over the entire treatment period in AM, pre-dose, instantaneous, total ocular symptoms scores (iTOSS) Mean change from baseline over the entire treatment period in AM rTOSS Mean change from baseline over the entire treatment period in PM rTOSS Mean change from baseline over the entire treatment period in individual (1) daily reflective, (2) AM pre-dose instantaneous, (3) AM reflective, and (4) PM reflective nasal symptom scores for eyes itching/ burning, eye tearing/watering, eye redness
Statistical Methods: The primary analysis method was the comparison of treatment groups (FFNS vs. placebo) using analysis of covariance with adjustments for baseline rTNSS, baseline eosinophils (positive or negative), age, and gender. The intent-to-treat (ITT) Population was used for all efficacy and safety analyses. The ITT population consisted of all randomized subjects who received at least one dose of study medication. The least squares mean changes for each treatment group were summarized and compared. The secondary efficacy measures concerning nasal symptoms were analyzed similarly to the primary analysis. One-hundred subjects were planned for this study, with 50 subjects assigned to each of the two treatment groups: fluticasone furoate nasal spray 110mcg and placebo nasal spray. This sample size was used to ensure the distance from the mean to the limit (½ width) of the 95 % confidence interval for the treatment effect was no larger than 0.666, assuming the standard deviation of 1.7 based on two previous VMR studies where the same assessment ratings were used..

Study Population: : Eligible male and female subjects must have been outpatients ≥ 12 years of age and met the following criteria: (1) signed informed consent or assent (2) could not be pregnant or planning to become pregnant and must have committed to use of birth control, (3) a diagnosis or evidence of air pollution as the predominant irritant trigger for their rhinitis symptoms that included a two-year history of irritant (non-allergic) rhinitis and evidence of rhinorrhea, nasal congestion and postnasal drip related to air pollution (4) indicated air pollution as the predominant trigger on the screening trigger questionnaire, (5) negative skin prick test response to seasonal/perennial allergens relevant to Bangkok and positive skin prick test response to histamine, and (6) normal sinus radiograph (Waters view) to rule out sinusitis. Subjects could not have had significant concomitant medical conditions and could not have used corticosteroids or other allergy medications within specified periods prior to Visit 1. Use of face masks (e.g. masks used for protection from air pollution and continuous positive airflow pressure [CPAP], saline nasal sprays and lavages, eye drops, and local, herbal and homeopathic treatments were also prohibited.		
	Placebo	FFNS 110mcg
Number of Subjects		
Planned, N	50	50
Randomised, N	49	53
Completed, n (%)	45 (92)	48 (91)
Total Number Subjects Withdrawn, N (%)	4 (8)	5 (9)
Withdrawn due to Adverse Events n (%)	2 (4)	0
Withdrawn due to Lack of Efficacy n (%)	1 (2)	1 (2)
Withdrawn for other reasons n (%)	1 (2)	4 (8)
Demographics	Placebo	FFNS 110mcg
N (ITT)	49	53
Females: Males	37/12	33/20
Mean Age, years (SD)	35.9 (10.89)	37.1 (12.78)
Asian, n (%)	49 (100%)	53 (100%)
Primary Efficacy Results:		
	Placebo	FFNS 110mcg
Mean Baseline (SE)	6.4 (0.17)	6.7 (0.17)
Difference in LS Mean Change between Treatments	-0.065	
95% Confidence Interval	-0.72, 0.59	
p-value	0.845	
Secondary Outcome Variable(s):		
	Placebo	FFNS 110mcg
Total Nasal Symptom Scores		
AM pre-dose iTNSS		
LS Mean Change (SE)	-1.82 (0.26)	-1.90 (0.24)
Difference in LS Mean Change between Treatments	-0.075	
95% CI	-0.76, 0.61	
AM rTNSS		
LS Mean Change (SE)	-2.13 (0.27)	-2.15 (0.24)
Difference in LS Mean Change between Treatments	-0.16	
95% CI	-0.70, 0.67	
PM rTNSS		
LS Mean Change (SE)	-2.09 (0.25)	-2.19 (0.23)
Difference in LS Mean Change between Treatments	-0.097	
95% CI	-0.76, 0.56	
Individual Nasal Symptoms		
Daily reflective		
Rhinorrhea		
LS Mean Change(SE)	-0.64 (0.09)	-0.72 (0.08)
Difference in LS Mean Change between Treatments	-0.078	
95% CI	-0.30, 0.15	

Nasal Congestion		
LS Mean Change (SE)	-0.75 (0.09)	-0.79 (0.08)
Difference in LS Mean Change between Treatments	-0.037	
95% CI	-0.27, 0.19	
Post-nasal Drip		
LS Mean Change (SE)	-0.70 (0.10)	-0.67 (0.09)
Difference in LS Mean Change between Treatments	0.034	
95% CI	-0.22, 0.28	
AM Pre-dose Instantaneous		
Rhinorrhea		
LS Mean Change(SE)	-0.52 (0.09)	-0.61 (0.09)
Difference in LS Mean Change between Treatments	-0.088	
95% CI	-0.33, 0.16	
Nasal Congestion		
LS Mean Change (SE)	-0.64 (0.09)	-0.71 (0.08)
Difference in LS Mean Change between Treatments	-0.070	
95% CI	-0.31, 0.17	
Post-nasal Drip		
LS Mean Change (SE)	-0.66 (0.10)	-0.58 (0.09)
Difference in LS Mean Change between Treatments	0.076	
95% CI	-0.19, 0.34	
AM Reflective		
Rhinorrhea		
LS Mean Change(SE)	-0.65 (0.09)	-0.72 (0.08)
Difference in LS Mean Change between Treatments	-0.067	
95% CI	-0.31, 0.17	
Nasal Congestion		
LS Mean Change (SE)	-0.75 (0.09)	-0.78 (0.08)
Difference in LS Mean Change between Treatments	-0.036	
95% CI	-0.27, 0.20	
Post-nasal Drip		
LS Mean Change (SE)	-0.73 (0.10)	-0.65 (0.09)
Difference in LS Mean Change between Treatments	0.078	
95% CI	-0.18, 0.34	
PM Reflective		
Rhinorrhea		
LS Mean Change(SE)	-0.63 (0.09)	-0.72 (0.09)
Difference in LS Mean Change between Treatments	-0.095	
95% CI	-0.32, 0.13	
Nasal Congestion		
LS Mean Change (SE)	-0.76 (0.09)	-0.79 (0.09)
Difference in LS Mean Change between Treatments	-0.031	
95% CI	-0.27, 0.21	
Post-nasal Drip		
LS Mean Change (SE)	-0.69 (0.10)	-0.68 (0.09)
Difference in LS Mean Change between Treatments	0.004	
95% CI	-0.25, 0.26	
Total Ocular Symptom Scores		
Daily rTOSS		
LS Mean Change (SE)	-0.77 (0.16)	-1.04 (0.14)
Difference in LS Mean Change between Treatments	-0.275	
95% CI	-0.69, 0.14	

AM pre-dose iTOSS		
LS Mean Change (SE)	-0.85 (0.17)	-0.98 (0.15)
Difference in LS Mean Change between Treatments	-0.127	
95% CI	-0.56, 0.31	
AM rTOSS		
LS Mean Change (SE)	-0.81 (0.17)	-0.96 (0.16)
Difference in LS Mean Change between Treatments	-0.144	
95% CI	-0.59, 0.30	
PM rTOSS		
LS Mean Change (SE)	-0.74 (0.16)	-1.13 (0.15)
Difference in LS Mean Change between Treatments	-0.382	
95% CI	-0.80, 0.04	
Individual Ocular Symptoms		
Daily reflective		
Eye Itching/Burning		
LS Mean Change (SE)	-0.32 (0.07)	-0.45 (0.06)
Difference in LS Mean Change between Treatments	-0.131	
95% CI	-0.31, 0.05	
Eye Tearing/Watering		
LS Mean Change (SE)	-0.29 (0.06)	-0.31 (0.06)
Difference in LS Mean Change between Treatments	-0.017	
95% CI	-0.18, 0.15	
Eye Redness		
LS Mean Change (SE)	-0.17 (0.06)	-0.28 (0.05)
Difference in LS Mean Change between Treatments	-0.111	
95% CI	-0.25, 0.03	
AM pre-dose instantaneous		
Eye Itching/Burning		
LS Mean Change (SE)	-0.35 (0.08)	-0.37 (0.07)
Difference in LS Mean Change between Treatments	-0.023	
95% CI	-0.23, 0.18	
Eye Tearing/Watering		
LS Mean Change (SE)	-0.30 (0.06)	-0.33 (0.06)
Difference in LS Mean Change between Treatments	-0.025	
95% CI	-0.19, 0.14	
Eye Redness		
LS Mean Change (SE)	-0.21 (0.05)	-0.27 (0.05)
Difference in LS Mean Change between Treatments	-0.055	
95% CI	-0.19, 0.08	
AM reflective		
Eye Itching/Burning		
LS Mean Change (SE)	-0.34 (0.07)	-0.42 (0.06)
Difference in LS Mean Change between Treatments	-0.071	
95% CI	-0.26, 0.11	
Eye Tearing/Watering		
LS Mean Change (SE)	-0.32 (0.07)	-0.29 (0.06)
Difference in LS Mean Change between Treatments	0.024	
95% CI	-0.15, 0.20	
Eye Redness		
LS Mean Change (SE)	-0.16 (0.06)	-0.23 (0.05)
Difference in LS Mean Change between Treatments	-0.078	
95% CI	-0.23, 0.07	

PM reflective		
Eye Itching/Burning		
LS Mean Change (SE)	-0.30 (0.07)	-0.48 (0.06)
Difference in LS Mean Change between Treatments	-0.176	
95% CI	-0.36, 0.01	
Eye Tearing/Watering		
LS Mean Change (SE)	-0.27 (0.06)	-0.33 (0.05)
Difference in LS Mean Change between Treatments	-0.055	
95% CI	-0.21, 0.10	
Eye Redness		
LS Mean Change (SE)	-0.19 (0.06)	-0.31 (0.05)
Difference in LS Mean Change between Treatments	-0.125	
95% CI	-0.28, 0.03	
Safety Results: An on therapy adverse event (AE) was defined as an AE with onset on or after the start date of study medication but not later than one day after the last date of study medication.		
	Placebo	FFNS 110mcg
Most Frequent Adverse Events – On-Therapy		
Subjects with any AE(s), n(%)	18 (37)	21 (40)
Cough	1 (2)	3 (6)
Migraine	1 (2)	2 (4)
Nasal Ulcer	1 (2)	2 (4)
Epistaxis	0	2 (4)
Back pain	0	1 (2)
Dry mouth	0	1 (2)
Facial pain	0	1 (2)
Hemicephalgia	0	1 (2)
Nasal discomfort	0	1 (2)
Nasopharyngitis	0	1 (2)
All On-therapy SAEs		
Upper respiratory tract infection (unrelated to treatment)	0	1 (2%)
Conclusion: Once-daily FFNS 110mcg did not demonstrate a significant treatment difference compared with placebo for the primary efficacy endpoint (LS mean difference = -0.065, p=0.845), and, therefore, a lack of efficacy in adults and adolescents ≥ 12 years of age with irritant rhinitis who had symptoms triggered predominantly by pollution. Overall, fluticasone furoate 110mcg was well tolerated.		
Publications: No citations		