

Mometasone furoate nasal spray in the treatment of nasal polyposis in Chinese patients: a double-blind, randomized, placebo-controlled trial

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Background: Although mometasone furoate nasal spray (MFNS) has demonstrated efficacy in nasal polyposis (NP) in Western populations, data in Asian populations is limited.

Methods: This randomized, double-blind study evaluated MFNS 200 μ g twice per day (BID) vs placebo in Chinese adults with bilateral nasal polyps (graded as 1, 2, or 3 by the investigator). A 14-day placebo run-in period was followed by a 16-week treatment period with MFNS 200 μ g BID vs placebo (1:1 ratio). The co-primary endpoints were change from baseline in nasal congestion/obstruction averaged over the first 4 weeks of treatment and change from baseline in the total polyp size score (sum of scores from the left and right nasal fossa) at week 16. Secondary endpoints included other sinonasal symptoms scores and safety outcomes such as monitoring laboratory measurements, vital signs, and adverse events (AEs).

Results: There were 748 patients randomized, 375 received MFNS 200 μ g BID and 373 received placebo. The between-treatment difference in least squares (LS) mean change from baseline in nasal congestion/obstruction over 4 weeks of treatment was -0.14 (95% confidence interval

[CI], -0.22 to -0.06) for MFNS vs placebo ($p = 0.0007$). The between-treatment difference in LS mean change from baseline in total polyp size score at week 16 was -0.30 (95% CI, -0.45 to -0.15) for MFNS vs placebo ($p < 0.0001$). Serious AEs were rare (0.5% and 0.8% in MFNS and placebo groups, respectively) and considered not drug-related. There were significantly more AEs of epistaxis with MFNS vs placebo ($p = 0.009$).

Conclusion: This study demonstrated that MFNS was effective and well tolerated in this population of adult, Chinese patients with NP. © 2015 ARS-AAOA, LLC.

Key Words:

nasal polyps; mometasone furoate; intranasal corticosteroids; nasal congestion; nasal obstruction; anterior rhinorrhea; postnasal drip; randomized controlled trial

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Nasal polyps are benign growths of the mucosa with clinical symptoms that include nasal obstruction, nasal discharge, postnasal drip, and loss of smell.^{1,2} These symptoms and the recurrent nature of nasal polyposis (NP) have a significant impact on patients' quality of life.^{3,4} Worldwide, the prevalence of NP is estimated to be up to 4%, suggesting a significant medical need for effective treatment.

The etiopathology of NP remains elusive. Although allergy is no longer suspected to play a role,⁵ other possible causes include bacterial infections, mucosal

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inflammation from bacterial superantigens, and fungal inflammation. Cystic fibrosis, primary ciliary dyskinesia, and aspirin hypersensitivity are also associated with NP.^{6,7}

Intranasal corticosteroids are frequently used to treat NP and have been shown to reduce polyp size, delay recurrence, and decrease the need for surgical excision.⁸ Mometasone furoate nasal spray (MFNS) has demonstrated efficacy in the treatment of NP in largely Western, white patient cohorts.^{9,10} Although evidence of positive treatment effects are well documented in Western patients with NP, important genetic variability exists among Western and non-Western populations, necessitating research in specific geographic populations. For example, research has shown that nasal mucosal remodeling and inflammation in Chinese patients with chronic rhinosinusitis (CRS) with nasal polyps is different from white patients.¹¹ Thus, data in Asian populations is needed by physicians and patients in non-western geographic locations to confirm that efficacy and safety are not altered by differential genetic or cultural factors. The present study was conducted to evaluate the efficacy and safety of MFNS in a population of Chinese patients with NP.

Patients and methods

This study (Clinical Trial Registry #NCT01386125, Schering Plough Study Number P05604/Merck Protocol #163) was conducted in 28 centers in China. The study was conducted in accordance with Good Clinical Practice guidelines.¹² The study protocol and informed consent statement were approved by local independent ethics committees.

Study design

This was a randomized, double-blind, placebo-controlled, parallel-group, 2-arm, multicenter study to evaluate the efficacy and safety of MFNS 200 µg twice per day (BID) in Chinese adults with NP. After a 14-day, single-blind, placebo run-in period, signs and symptoms of polyps were evaluated at screening visit 1 (graded on a scale from 0 = none to 3 = severe) and bilateral polyp size was graded by endoscopy. Patients recorded symptoms each day until visit 2 (baseline). At baseline, patients were randomized (1:1 ratio) according to a computer-generated allocation schedule to receive MFNS 200 µg BID or matching placebo nasal spray. Patients were treated for 16 weeks and were evaluated on visit 3 (day 8), visit 4 (week 4), visit 5 (week 8), visit 6 (week 12), and visit 7 (week 16).

Study medication was supplied for double-blind administration in a treatment kit labeled with study number, subject number, and dosing instructions. Disclosure envelopes corresponding to the individual treatments were provided to each site. Blinding was broken in the case of emergency only (eg, for serious adverse events). MFNS was supplied in a metered-dose manual pump spray containing an aqueous suspension of mometasone furoate monohydrate equivalent to 0.05% wt/wt mometasone furoate calculated

on the anhydrous basis. The aqueous medium contained glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, sodium citrate, 0.25% wt/wt phenylethyl alcohol, citric acid, benzalkonium chloride, and polysorbate 80.

Investigators performed an endoscopy at each visit. Polyps were graded by size and extent in both the left and right nasal fossa on a scale of 0 to 3 (0 = no polyps; 1 = polyp in middle meatus, not reaching below the inferior border of the middle turbinate; 2 = polyp reaching below the inferior border of the middle turbinate but not the inferior border of the inferior turbinate; and 3 = large polyp reaching to or below the lower border of the inferior turbinate or polyps medial to the middle turbinate). The sum of left and right nasal fossa polyp scores gave the total bilateral polyps grade. Investigators also evaluated therapeutic response at each visit on a qualitative scale ranging from complete relief of symptoms to no relief. Patients scored symptoms (nasal congestion/obstruction, loss of sense of smell, anterior rhinorrhea, and postnasal drip) each morning on a diary card immediately before dosing on a scale from 0 to 3 (0 = none; 1 = mild; 2 = moderate; 3 = severe). Treatment compliance was evaluated at visits 3 through 7 by weighing medication bottles without the patient's knowledge. Compliance was defined as use of 59% to 138% of the reference study drug bottle weight (compliance is normally defined as the use of 70% to 120% of study drug bottle weight, but the range was increased because the reference bottle weight could vary by 15%).

Patients

Patients were ≥18 years of age, Chinese, with a diagnosis of bilateral nasal polyps (graded as 1, 2, or 3 by the investigator on each side), and had clinically significant nasal congestion/obstruction (average morning score ≥2 for each of the last 7 days of the 14-day run-in period). Patients with asthma were included if they had a documented forced expiratory volume in 1 second (FEV1) ≥80% of the predicted value within 6 months of screening and no exacerbations within 30 days of screening. Inhaled corticosteroid users were on a moderate, stable regimen of beclomethasone dipropionate 800 mg/day or equivalent for 1 month before screening and remained on a stable regimen throughout the study.

Patients with a history of seasonal allergic rhinitis within the past 2 years were excluded. Patients having sinus or nasal surgery within the previous 6 months, a history of 3 or more nasal surgeries in the past, or a history of any procedure preventing an accurate grading of polyps was also excluded. Patients with presumed fibrotic nasal polyps, or complete/near-complete nasal obstruction were also excluded. Additionally, patients with the following diagnoses were excluded: nasal septal deviation requiring corrective surgery; nasal septal perforation; acute sinusitis, nasal infection, or upper respiratory tract/nasal infection at (or within 2 weeks of) screening; ongoing rhinitis

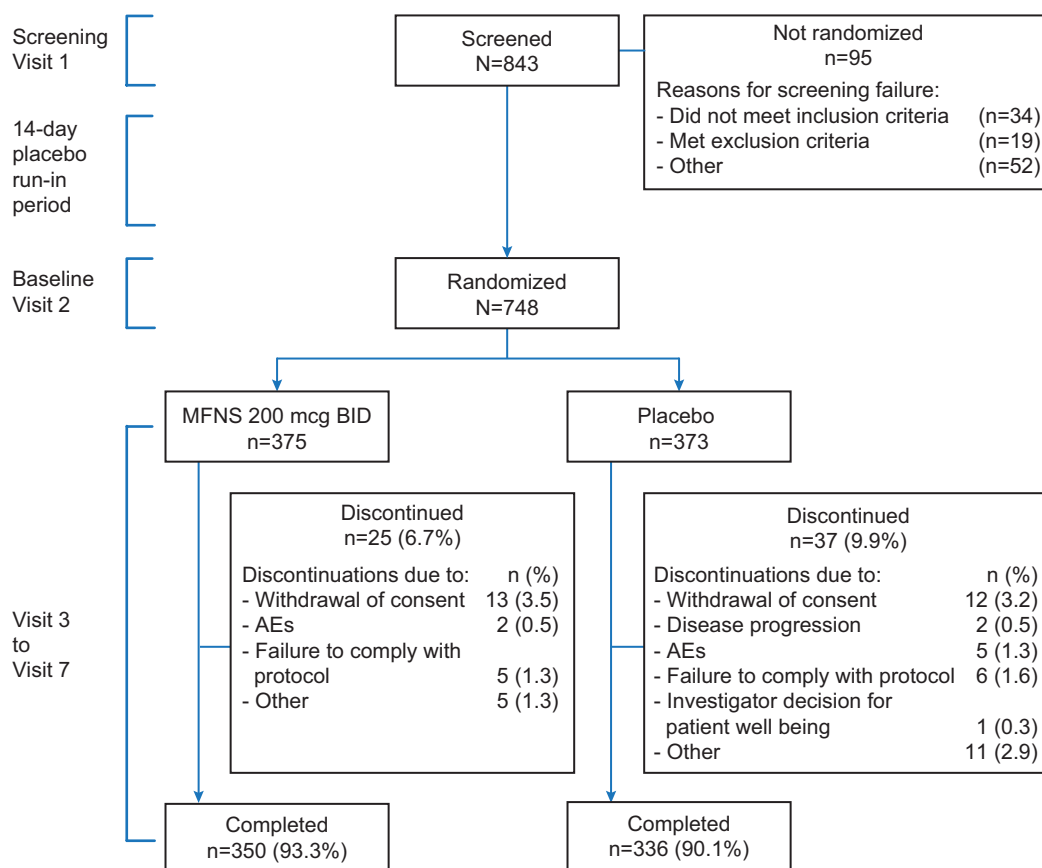


FIGURE 1. CONSORT diagram detailing accounting of patients throughout the study. AE = adverse event; BID = twice per day; CONSORT = Consolidated Standards of Reporting Trials; MFNS = mometasone furoate nasal spray.

medicamentosa; Churg-Strauss syndrome; dyskinetic ciliary syndromes; cystic fibrosis; glaucoma or a history of posterior subcapsular cataracts; allergies to corticosteroids or aspirin; or any clinically significant disease that would interfere with the evaluation of therapy. The following medications were prohibited during the study: nasal sodium cromolyn; nasal atropine or ipratropium bromide; guaifenesin; oral/intramuscular/intranasal corticosteroids (except oral inhaled corticosteroids for asthma or mild-strength or mid-strength topical corticosteroids for dermatologic purposes); antihistamines; decongestants; topical, oral, or ocular anti-inflammatory drugs; nonsteroidal anti-inflammatory drugs; or topical nasal or oral antifungal agents.

Efficacy evaluation

The co-primary efficacy objectives were to (1) evaluate the efficacy of MFNS 200 μ g BID with respect to nasal congestion/obstruction; and (2) evaluate the efficacy of MFNS 200 μ g BID with respect to bilateral polyps grade. The secondary efficacy objectives were to evaluate efficacy with respect to anterior rhinorrhea, postnasal drip, loss of smell, proportion of patients that demonstrated improvement, and the investigator's evaluation of therapeutic response.

The co-primary efficacy endpoints were (1) change from baseline in nasal congestion/obstruction averaged over the

first 4 weeks of the treatment period; and (2) change from baseline in total polyp size score at week 16. Secondary endpoints included: change from baseline in nasal congestion/obstruction averaged over weeks 5–8, weeks 9–12, and weeks 13–16; change from baseline in the total polyp size score evaluated at week 4, week 8, week 12; change from baseline in anterior rhinorrhea score averaged weeks 1–4, weeks 5–8, weeks 9–12, and weeks 13–16; change from baseline in postnasal drip score averaged over weeks 1–4, weeks 5–8, weeks 9–12, and weeks 13–16; change from baseline in loss of smell score averaged over weeks 1–4, weeks 5–8, weeks 9–12, and weeks 13–16; proportion of patients that demonstrate improvement; the investigator's evaluation of therapeutic response.

Safety assessments

Safety assessments included adverse event (AE) reporting, laboratory tests, vital signs, and physical examination. AEs were recorded throughout the study, with severity graded as mild, moderate, severe or life-threatening, and a relationship to treatment assigned by investigators. At all visits, vital signs were measured. Clinical laboratory tests and a physical examination were performed at visit 1 and visit 7. Laboratory tests that were conducted included the testing of hematology, chemistry, and urinalysis. Hematology tests

TABLE 1. Patient demographics

	MFNS (n = 375)	Placebo (n = 373)
Age (years)		
Mean $\pm$ SD	46.8 $\pm$ 13.5	46.8 $\pm$ 13.8
Median	48	49
Range	18–79	19–73
Gender, n (%)		
Male	224 (59.7)	239 (64.1)
Female	151 (40.3)	134 (35.9)
Time since diagnosis of nasal polyps (months)		
Mean $\pm$ SD	40.9 $\pm$ 93.4	38.6 $\pm$ 89.8
Median	0.8	0.8
Range	0–549	0–626
Family history of nasal polyps, n (%)		
Yes	40 (10.7)	23 (6.2)
No	335 (97.3)	350 (93.8)
Concurrent asthma status, n (%)		
Yes	10 (2.7)	13 (3.5)
No	365 (97.3)	360 (86.5)
Sensitivity to antigen, n (%)		
Yes	16 (4.3)	19 (5.1)
No	294 (78.4)	293 (78.6)
Unknown	65 (17.3)	61 (16.4)
History of sinus surgery, n (%)		
Yes	92 (24.5)	85 (22.8)
No	283 (75.5)	288 (77.2)
Baseline values for efficacy endpoints, mean $\pm$ SD		
Baseline congestion/obstruction	2.1 $\pm$ 0.3	2.1 $\pm$ 0.4
Baseline total polyp size	3.6 $\pm$ 1.1	3.7 $\pm$ 1.1
Baseline anterior rhinorrhea score	1.5 $\pm$ 0.9	1.4 $\pm$ 0.8
Baseline postnasal drip score	1.15 $\pm$ 0.8	1.14 $\pm$ 0.9
Baseline loss of smell score	1.8 $\pm$ 1.0	1.7 $\pm$ 1.0

MFNS = mometasone furoate nasal spray; SD = standard deviation.

included red blood cell (RBC) count, hemoglobin, platelets count, white blood cell (WBC) count, and WBC differential. Chemistry tests included total protein, albumin, total bilirubin, alkaline phosphatase, alanine transaminase (ALT), aspartate transaminase (AST), blood urea nitrogen, creatinine, glucose, potassium, and sodium chloride. Urinalysis included protein, glucose, blood, WBC, ketones, and, in female subjects only, beta human chorionic gonadotropin (HCG).

Statistical methods

The study included 2 co-primary hypotheses: (1) treatment with MFNS would decrease the symptom of nasal congestion/obstruction compared to placebo; and (2) treatment with MFNS would decrease the size of nasal polyps compared to placebo. Statistical superiority vs placebo was determined at the 2-sided 0.05 significance level.

The full analysis set (FAS) was used for the primary analysis of efficacy and consisted of all randomized patients who received ≥ 1 dose of study medication and who had baseline and/or ≥ 1 postbaseline efficacy measurement. The safety set, used for the analysis of safety, consisted of all randomized patients who received ≥ 1 study treatment dose. Inclusion in the analysis required ≥ 1 laboratory or vital sign measurement after dosing.

This study was designed to have a sample size of 740 patients (370 patients per arm) and to have 90% power to detect a 0.30-point difference in change from baseline in average congestion/obstruction over the first 4 weeks (assuming a standard deviation [SD] of 0.55 and a 2-sided significance level of 0.05). A 0.35-point difference between MFNS and placebo in change from baseline to week 16 in bilateral polyp size was to be detected with $\sim 90\%$ power assuming an SD of 1.70 and a 2-sided significance level of 0.05.

The analyses of the change from baseline in nasal congestion/obstruction, anterior rhinorrhea score, postnasal drip score, and loss of smell score were adjusted for treatment (fixed effect) and baseline (covariate) using analysis of covariance (ANCOVA). A constrained longitudinal data analysis (cLDA) was used to analyze polyp size and investigator's evaluation of therapeutic response. The cLDA included all available measurements from baseline through the last visit and included treatment, time (categorical),

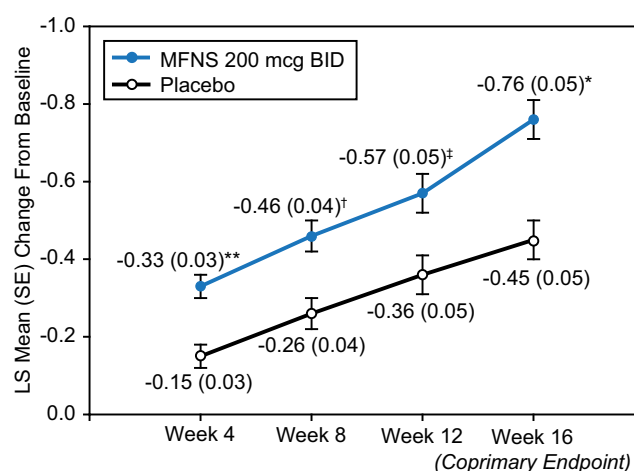


FIGURE 2. LS mean (SE) change from baseline in total polyp size score at specified time periods. Week 16 is a co-primary endpoint. Weeks 4, 8, and 12 are secondary endpoints. MFNS 200 μ g BID was superior to placebo over each period. * $p < 0.0001$; ** $p = 0.0001$; † $p = 0.0006$; ‡ $p = 0.0013$. AE = adverse event; BID = twice per day; LS = least squares; MFNS = mometasone furoate nasal spray; SE = standard error.

TABLE 2. Other secondary endpoints*

	MFNS	Placebo	LS mean difference (95% CI) [p value]
Change from baseline in anterior rhinorrhea score			
Averaged over weeks 1–4	-0.24 ± 0.03	-0.10 ± 0.03	-0.14 (-0.22 to -0.06) [0.0007]
Averaged over weeks 5–8	-0.43 ± 0.03	-0.24 ± 0.04	-0.20 (-0.29 to -0.10) [<0.0001]
Averaged over weeks 9–12	-0.46 ± 0.04	-0.30 ± 0.04	-0.16 (-0.26 to -0.05) [0.0028]
Averaged over weeks 13–16	-0.53 ± 0.04	-0.37 ± 0.04	-0.16 (-0.27 to -0.05) [0.0030]
Change from baseline in postnasal drip score			
Averaged over weeks 1–4	-0.11 ± 0.03	-0.05 ± 0.03	-0.07 (-0.14 to 0.00) [0.0637]
Averaged over weeks 5–8	-0.26 ± 0.03	-0.17 ± 0.03	-0.09 (-0.18 to 0.00) [0.0453]
Averaged over weeks 9–12	-0.33 ± 0.03	-0.23 ± 0.03	-0.10 (-0.19 to 0.00) [0.0405]
Averaged over weeks 13–16	-0.37 ± 0.03	-0.28 ± 0.03	-0.08 (-0.18 to 0.01) [0.0879]
Change from baseline in loss of smell score			
Averaged over weeks 1–4	-0.12 ± 0.02	-0.05 ± 0.02	-0.07 (-0.14 to 0.00) [0.0387]
Averaged over weeks 5–8	-0.28 ± 0.03	-0.16 ± 0.03	-0.13 (-0.22 to -0.03) [0.0080]
Averaged over weeks 9–12	-0.35 ± 0.04	-0.23 ± 0.04	-0.12 (-0.22 to -0.02) [0.0189]
Averaged over weeks 13–16	-0.41 ± 0.04	-0.25 ± 0.04	-0.15 (-0.26 to -0.05) [0.0037]
Investigator's evaluation of therapeutic response			
Day 8	3.0 ± 0.04	3.2 ± 0.04	-0.1 (-0.3 to 0.0) [0.0109]
Week 4	2.6 ± 0.04	2.9 ± 0.04	-0.3 (-0.4 to -0.2) [<0.0001]
Week 8	2.4 ± 0.05	2.8 ± 0.05	-0.3 (-0.4 to -0.2) [<0.0001]
Week 12	2.3 ± 0.05	2.6 ± 0.05	-0.3 (-0.4 to -0.2) [<0.0001]
			Odds ratio (95% CI) [p value]
Proportion of patients who demonstrate improvement	37.9%	24.7%	1.88 (1.37 to 2.59) [0.0001]

*Values are LS mean $\pm$ SE except where indicated otherwise.

CI = confidence interval; LS = least squares; MFNS = mometasone furoate nasal spray; SE = standard error.

and treatment-by-time interaction as explanatory variables as terms. An unstructured covariance matrix was used to model the correlation among repeated measurements. For categorical secondary endpoints, a Cochran-Mantel-Haenszel test adjusting for center was applied.

Results

Patient disposition and characteristics

In this study, 843 patients were screened and 748 patients randomized to MFNS 200 μ g BID ($n = 375$) or placebo ($n = 373$) (Fig. 1). Baseline characteristics were comparable between the 2 treatment groups (Table 1). Patients were Chinese with a mean age of 46.8 years. Only 2.7% (MFNS) and 3.5% (placebo) of patients reported concurrent asthma. There were 686 (91.7%) patients who completed the study; the discontinuation rate for both treatment groups was comparable (Fig. 1). The compliance rate was 95.5% (MFNS) and 94.8% (placebo).

Efficacy

MFNS was superior to placebo for both primary efficacy endpoints ($p < 0.05$). The least squares (LS) mean change from baseline in nasal congestion/obstruction averaged over the first 4 weeks of the treatment period was -0.56 (MFNS) and -0.42 (placebo). The between-treatment difference (MFNS minus placebo) in LS means was -0.14 (95% confidence interval [CI], -0.22 to -0.06) ($p = 0.0007$) (Fig. 2, Table 2). The LS mean change from baseline in total polyp size score at week 16 was -0.76 (MFNS) and -0.45 (placebo). The between-treatment difference (MFNS minus placebo) in LS means was -0.30 (95% CI, -0.45 to -0.15) ($p < 0.0001$) (Figs. 2 and 3, Table 2).

MFNS was superior to placebo for all other time points evaluated with regard to the change from baseline in nasal congestion/obstruction endpoint (nominal p values < 0.05) and all other time points (ie, week 4, week 8, and week 12) for the change from baseline in total polyp size score

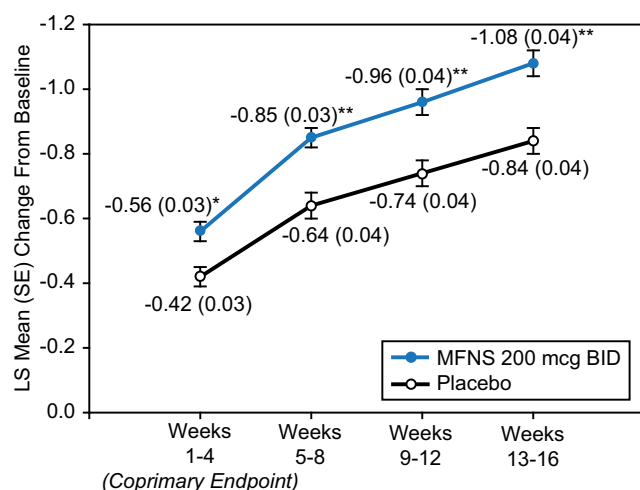


FIGURE 3. LS mean (SE) change from baseline in nasal congestion/obstruction averaged over specified time periods. Weeks 1–4 is a coprimary endpoint. Weeks 5–8, weeks 9–12, and weeks 13–16 are secondary endpoints. MFNS 200 μ g BID was superior to placebo over each period. * $p = 0.0007$; ** $p < 0.0001$. AE = adverse event; BID = twice per day; LS = least squares; MFNS = mometasone furoate nasal spray; SE = standard error.

endpoint (nominal $p < 0.05$). Changes from baseline in anterior rhinorrhea score averaged over weeks 1–4, weeks 5–8, weeks 9–12, and weeks 13–16 were superior for MFNS vs placebo (nominal $p < 0.05$). Changes from baseline in postnasal drip score were superior for MFNS vs placebo for weeks 5–8 and weeks 9–12 (nominal $p < 0.05$); MFNS was numerically better than placebo at weeks 1–4 and weeks 13–16. MFNS was superior to placebo for changes from

baseline in loss of smell score averaged over weeks 1–4, weeks 5–8, weeks 9–12, weeks 13–16 (nominal $p < 0.05$), and for patients who demonstrated improvement (nominal $p = 0.0001$). MFNS also demonstrated improvement in investigator's evaluation of therapeutic response vs placebo at all time points (nominal $p < 0.05$) (Table 2).

Safety

The proportion of patients with AEs was relatively low in both groups: 18.9% (MFNS) and 18.5% (placebo). Drug-related AEs occurred in 5.6% (MFNS) and 4.3% (placebo) of patients. Serious AEs occurred in 0.5% (MFNS) and 0.8% (placebo) of patients discontinuations due to AEs occurred in 0.5% (MFNS) and 1.1% (placebo) of patients. None of the serious AEs were judged to be related to the study drug and no deaths were reported.

The most commonly reported AEs were nasopharyngitis, upper respiratory tract infection, and epistaxis. The AE of epistaxis was prespecified to be compared between the 2 treatment groups; significantly more MFNS patients vs placebo experienced epistaxis ($p = 0.009$). No new or unexpected AEs occurred in this study (Table 3).

Discussion

NP is a condition that has a considerable detrimental impact on quality of life. Topical steroid therapy is an important treatment for CRS with nasal polyps.¹ Our results confirm that MFNS provides efficacy in Chinese patients and provides patients in Asia an important treatment option that is supported by clinical evidence.¹³

TABLE 3. Summary of safety*

	MFNS (n = 375) n (%)	Placebo (n = 373) n (%)	Difference vs placebo Estimate (95% CI)
≥1 AE	71 (18.9)	69 (18.5)	0.4 (−5.2 to 6.0)
With drug-related AEs	21 (5.6)	16 (4.3)	1.3 (−1.9 to 4.6)
With serious AEs	2 (0.5)	3 (0.8)	−0.3 (−1.9 to 1.2)
Discontinued due to AEs	2 (0.5)	4 (1.1)	−0.5 (−2.3 to 1.0)
Prespecified AE of interest			
Epistaxis	14 (3.7)	4 (1.1)	2.7 (0.5 to 5.2)
Most common AEs (≥4 patients within treatment group)			
Nasopharyngitis	7 (1.9)	9 (2.4)	−0.5 (−2.9 to 1.7)
Pharyngitis	4 (1.1)	2 (0.5)	0.5 (−1.0 to 2.2)
Upper respiratory tract infection	5 (1.3)	10 (2.7)	−1.3 (−3.7 to 0.7)
Urinary tract infection	4 (1.1)	0 (0.0)	1.1 (0.0 to 2.7)
Alanine aminotransferase increased	5 (1.3)	4 (1.1)	0.3 (−1.6 to 2.1)
Cough	6 (1.6)	2 (0.5)	1.1 (−0.5 to 3.0)
Oropharyngeal pain	2 (0.5)	5 (1.3)	−0.8 (−2.6 to 0.7)

*Values are n (%) and estimate (95% CI), as indicated.

AE = adverse event; CI = confidence interval; MFNS = mometasone furoate nasal spray.

In this study, Chinese patients with NP received clinically significant improvement with MFNS in both co-primary efficacy endpoints and the majority of secondary efficacy endpoints over the 16-week treatment period. No loss of effect was observed over the 16-week treatment period. Anterior rhinorrhea and loss of smell scores also demonstrated statistically superior efficacy vs placebo at all time points. Additionally, MFNS was statistically superior to placebo at weeks 5–8 and weeks 9–12 for postnasal drip score, and numerically higher at weeks 1–4 and weeks 13–16 for this endpoint.

These results are generally consistent with 2 pivotal studies that were done with MFNS in patients with NP in Western populations, although there were some notable differences. Change from baseline in anterior rhinorrhea and postnasal drip scores were lower in the MFNS and placebo groups compared with the previous studies.^{9,10} Several factors may contribute to the slight differences observed in this trial vs the previous trials in Western populations (both of which had results relatively consistent with each other). The proportion of patients with asthma/history of asthma was lower in this study vs the previous studies. Lower baseline polyp size, lower anterior rhinorrhea, and lower baseline postnasal drip scores were also reported in this study compared with the previous studies. These factors may contribute to a lower change from baseline in anterior rhinorrhea and postnasal drip scores.^{9,10}

MFNS and placebo patients reported AEs with similar frequency although epistaxis was significantly higher with MFNS vs placebo. Serious AEs and discontinuations due to AEs were rare, occurred with similar frequency between both groups, and none were considered drug related.

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Idiopathic CRS with NP comprises the majority of NP cases¹ and is dominated by T-helper 2 (TH2)-mediated (ie, eosinophilic) responses. Although NP symptoms appear consistent worldwide, the level of eosinophilic involvement may represent a differentiating factor among white and Asian populations. NP has been shown to have a strong eosinophilic component in white populations due to upregulation of interleukin-5, eotaxin, and eosinophilic cationic protein.¹⁴ In contrast, NP cases in Asian populations largely show a neutrophilic involvement.^{15–17} Data showing that NP treatments are not sensitive to ethnic variability are important for prescribing physicians.

The present study was not designed to assess eosinophilia in Chinese patients. Our data suggest a lack of ethnic variability in treatment response, although there was no direct comparison among Chinese and Western populations. However, from this study, despite evidence showing different inflammatory mechanisms between Asian and Western patients, we can draw a similar conclusion as previous studies in Western populations; that is, MFNS provided clinically important efficacy in the treatment of NP in Chinese patients.

Conclusion

In summary, MFNS was effective and well tolerated in this population of adult, Chinese patients with NP. ☼

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