

Efficacy and safety of olopatadine-mometasone combination nasal spray for the treatment of seasonal allergic rhinitis

BACKGROUND

- Allergic rhinitis (AR) is one of the most common chronic diseases in pediatric and adult patients.
- Combination treatments that contain an intranasal antihistamine with an intranasal corticosteroid are more effective in controlling AR symptoms than monotherapy alone.
- GSP301 is an investigational drug with the antihistamine olopatadine hydrochloride and the corticosteroid mometasone furoate developed as a single nasal spray for the treatment of seasonal allergic rhinitis symptoms (SAR).

OBJECTIVE

- To evaluate the efficacy, safety, and tolerability of GSP301 nasal spray vs. placebo and the individual monotherapy formulations for 14 days of treatment in adult and adolescent patients with SAR.

METHODS

- **Design:** Phase 3, double-blind, randomized, parallel study; Duration: 14 days
- **Inclusion criteria:** Patients 12 years or older with a clinical history of SAR for 2 years or more before screening for the relevant seasonal allergen during the fall or mountain cedar allergy season with a positive skin prick test, a minimum average morning and evening 12-hour reflective Total Nasal Score (rTNSS) of 8 or higher out of 12 and a morning congestion score of 2 or more at the screening visit.
- **Exclusion criteria:** Any known history of: nasal polyps, other clinical respiratory tract malformations, nasal structure abnormalities, nasal trauma, acute or significant chronic sinusitis or chronic purulent postnasal drip, significant atopic dermatitis or rhinitis medicamentosa, active pulmonary disorder or infection, upper respiratory tract or sinus infection 14 days or more before screening, or the development of respiratory infections during the placebo run-in period. Patients not allowed to travel outside the known pollen area for the investigative site for certain periods of time. Patients could not have impaired hepatic function, GI disease, subcapsular cataracts, glaucoma, systemic infection, malignant tumor, current neurological condition, CV disease, renal or endocrine disease or known failure to show allergic rhinitis symptom improvement with any approved monotherapy component of GSP301.
- **Primary outcome:** The mean change from baseline to the end of the 14-day treatment period in average morning and evening 12-hour rTNSS.
- **Secondary outcomes:** The mean change from baseline to the end of the 14-day treatment in average morning and evening 12-hour iTNSS and average morning and evening 12-hour rTOSS, onset of action assessment, and mean change from baseline to day 15 in the overall RQLQ (S) score.
- 1176 patients (294 each group) received either
 - GSP301: 2 sprays per nostril twice daily
 - Olopatadine: 2 sprays per nostril twice daily
 - Mometasone: 2 sprays per nostril twice daily
 - Placebo: 2 sprays per nostril twice daily
- Power of 90% assumed with an enrollment of 279 patients per treatment group.

RESULTS

- 1147 patients completed the study.

- **Primary outcome:** GSP301 showed statistical and clinically significant improvements in average morning and evening 12-hour rTNSS from baseline to the end of 14-day treatment vs placebo ($P < 0.001$) and vs. each individual monotherapy (olopatadine $P = 0.3$ and mometasone $\{ = 0.2$).
- **Secondary outcome:** GSP301 showed statistically significant improvement on all average morning and evening reflective and instantaneous individual nasal symptoms vs. placebo during the 14-day treatment period ($P < .001$ for all) shown on Table 3.
- **Author's conclusion:** The results showed that GSP301 is efficacious and well tolerated vs. placebo for the treatment of nasal and ocular symptoms associated with SAR in adults and adolescent patients 12 years and older.

STRENGTHS

- Double-blind design
- Large sample size

LIMITATIONS

- Results cannot be compared to azelastine-fluticasone due to the patients in this study being exposed to fall or mountain cedar allergens.
- Study only looked at SAR nasal and ocular symptoms, but some patients experience allergy symptoms year round.
- Follow-up not reported
- Adherence not reported
- Length of the study was only 14 days long, but most patients use these products for longer than 14 days.
- Most of the patients in the study population were white females; therefore no diversity in the study population making it difficult to extrapolate the data.
- The study was biased due to conflicts of interests affecting how the results were reported.

CONCLUSION

- GSP301 was shown to be statistically effective for the treatment of nasal and ocular symptoms associated with SAR in adults and patients 12 years and older.
- Small magnitude of difference between GSP301 and individual treatments in comparing average morning and evening reflective and instantaneous individual nasal symptom scores.
- Future studies are needed to compare azelastine-fluticasone and GSP301 to compare overall efficacy and onset of action. This is their biggest competitor based on the results from the azelastine-fluticasone vs. placebo.

Reference: Gross, GN., Berman, G., Amar. NJ., Cracta CF., Tantry, SK. Efficacy and safety of olopatadine-mometasone combination nasal spray for the treatment of seasonal allergic rhinitis. *Ann Allergy Asthma Immunol.* Jun 2019;122(6):630-638.

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