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# A proof-of-concept study of the effect of a novel H3-receptor antagonist in allergen-induced nasalcongestion.

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## Abstract

### BACKGROUND:

H1-receptor inverse agonists are used effectively for treating several symptoms of allergic rhinitis, including nasal itching, rhinorrhea, and sneezing, although most agents are not very effective in treating nasal congestion.

### OBJECTIVE:

This study evaluated the relative efficacy of a novel selective H3-receptor antagonist, JNJ-39220675, in preventing nasalcongestion induced by exposing participants with ragweed allergy to ragweed allergen in an environmental exposure chamber model.

### METHODS:

In this single-dose, patient-blind, double-dummy, placebo- and active-controlled, phase IIa cross-over study, 53 participants were randomized to JNJ-39220675 plus placebo, placebo plus pseudoephedrine, or only placebo. The primary efficacy assessment was change in nasal patency assessed by measuring the minimal cross-sectional area of the nasal cavity by using acoustic rhinometry. Secondary assessment included total nasal symptom scores (TNSSs) over the 8-hour environmental exposure chamber exposure period.

### RESULTS:

Smaller decreases in minimal cross-sectional area were observed after JNJ-39220675 (least square mean difference, -0.126; P = .06) and pseudoephedrine (least square mean difference, -0.195; P = .004) treatment compared with placebo. The means for the baseline-adjusted area under the curve of TNSSs were significantly smaller for JNJ-39220675 (P = .0003) and pseudoephedrine (P = .04) versus placebo. JNJ-39220675 was significantly effective in treating all 4 individual symptoms ($P \leq .05$ for all scores) compared with placebo, whereas pseudoephedrine only showed a trend for improvement in individual symptom scores of the TNSS. Insomnia was the most frequent adverse event (17.3%) associated with JNJ-39220675 treatment.

### CONCLUSION:

Prophylactic treatment with the H3-antagonist JNJ-39220675 relieved allergen-induced nasal congestion by using standard nasal symptom scoring; however, in contrast to pseudoephedrine, it only showed a trend for increasing nasal patency by using objective measures.