

# Patients with mild persistent asthma, low sputum eosinophils respond equally well to inhaled corticosteroids as placebo

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A study of nearly 300 patients with mild persistent asthma found that inhaled steroids—long considered the gold standard for asthma

treatment—were no more effective than placebo in nearly three-fourths of the study patients, all over age 12. Inhaled steroids were better than placebo for a subset of the patients who had high levels of a particular type of inflammatory cells, called eosinophils, in their sputum, but they represented about a fourth of patients enrolled in the trial.

The study was funded by the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health, and appeared online on May 19 in the *New England Journal of Medicine (NEJM)*. The publication coincides with the study's presentation at the international conference of the American Thoracic Society, which takes place in Dallas.

The research highlights the need for developing more [effective treatments](#) for [asthma](#) and suggests that it may be possible to target particular therapies to subsets of patients, such as those with high or low eosinophils. New approaches to treating the "low eosinophil" group could be especially helpful for improving the overall effectiveness of treatments for mild asthma, the most common type of this respiratory condition.

"We're intrigued by the results of this study and believe it raises questions about the way doctors manage mild persistent asthma," said Stephen Lazarus, M.D., lead study author and a professor of medicine at the University of California, San Francisco. "We're not saying that steroids are unimportant for mild asthma, but our study does suggest that [treatment](#) guidelines should be re-evaluated for patients with mild persistent asthma who have low sputum eosinophils."

James Kiley, Ph.D., director of the Division of Lung Diseases at NHLBI, said the research underscored the value of customizing treatments to help people with asthma. "This study adds to a growing body of evidence that different patients with mild asthma should be treated differently,

perhaps using biomarkers like sputum eosinophils to select which drugs should be used—a precision medicine approach," he said.

Asthma affects nearly 25 million Americans, according to the Centers for Disease Control and Prevention. Despite significant research strides, increasing numbers of people continue to have poorly controlled asthma. Mild persistent asthma is characterized by symptoms such as coughing, wheezing, and chest tightness, symptoms that occur less frequently than in people with severe asthma and are generally easier to control with steroids. However, daily steroid use can have adverse side effects over time, including weight gain and diabetes, and, at \$200 to \$400 per inhaler, can be expensive. A growing number of studies suggest that it may be possible to manage mild persistent asthma safely without daily steroid use.

In the quest to improve treatments for this type of asthma, researchers in the current study focused on sputum eosinophils, white blood cells found in the lung that can serve as biomarkers of airway inflammation. Biomarkers are generally used to guide treatment only in the most severe forms of asthma. Past studies have estimated that about half of the population with mild persistent asthma have less than 2% sputum eosinophils and that most people with low eosinophils do not respond well to steroid treatment. But laboratory tests to measure sputum eosinophils are relatively complex and not routinely used in most clinics.

The multicenter study included 295 people over the age of 12 with mild persistent asthma. The researchers further divided the group based on low or high sputum eosinophil levels (low = less than 2%; high = greater than or equal to 2%). The researchers assigned the participants in random sequence to three treatment groups for 12-week periods: inhaled steroids; long-acting muscarinic antagonists (LAMA), a nonsteroidal treatment for uncontrolled asthma; or placebo. By the end

of the study, every participant had received each treatment. The inhaled steroid used in this study was mometasone and the LAMA drug was tiotropium.

The researchers were surprised to find that nearly 73% of the participants, or 221 people, were classified as having low sputum eosinophils, a much higher frequency than expected. Among those participants who were classified as "Eos-low," the number who responded better to active treatment with steroids was no different than the number who responded better to placebo. By contrast, those who were classified as "Eos-high" were nearly three times as likely to respond to inhaled steroids than placebo.

Among those who were 'Eos-low' and had a better response to one of the treatments, 60% had superior results on LAMA, versus 40% who had better symptom control on placebo. While Lazarus cautioned that this difference is not large enough to conclude that [patients](#) are more likely to do better on LAMA drugs, he said it does highlight the need to study alternatives to inhaled steroids in [mild asthma](#). The researchers emphasized that for now people with asthma should continue to follow their doctor's recommendations regarding their treatments.

Provided by NIH/National Heart, Lung and Blood Institute

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