

Study shows combination drug therapy for asthma patients is safe

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A post-marketing safety study mandated by the U.S. Food and Drug Administration has shown that a combination drug therapy for the treatment of asthma is safe and effective.

The therapy tested consisted of a long-acting beta agonist, formoterol, added to an inhaled glucocorticoid, budesonide.

"Our study showed no significant increase in serious adverse events in the combination therapy," said Stephen Peters, M.D., Ph.D., professor of pulmonary, critical care, allergy and immunologic diseases at Wake Forest Baptist Medical Center and lead author of the study.

"A large number of studies have shown that this type of combination therapy really helps [asthma control](#) and decreases symptoms. Our findings, in combination with results from another FDA-mandated safety study, are very reassuring to those of us who treat asthmatic patients."

The study is published in the Sept. 1 issue of the *New England Journal of Medicine*.

In this multicenter, double-blind, 26-week study, the scientists evaluated whether the addition of formoterol to budesonide maintenance therapy increased the risk of serious [asthma](#)-related events in patients with moderate to [severe asthma](#). Study participants were age 12 or older, had [persistent asthma](#), received daily asthma medication and had one to four

exacerbations in the previous year.

Of the 11,693 patients enrolled in the study, an asthma-related event occurred in 43 patients who received the combination therapy of budesonide and formoterol and in 40 patients who received only budesonide. Two asthma-related deaths were reported in the combination arm of the study and none in the single-therapy group, which is not statistically significant.

In addition, a secondary finding showed a 16.5 percent decrease in [asthma exacerbations](#) in the [combination therapy](#) group as compared to the group receiving budesonide.

Overall, the researchers found that treatment with budesonide-formoterol was associated with a lower risk of asthma exacerbations than budesonide and a similar risk of serious asthma-related events.

Provided by Wake Forest University Baptist Medical Center

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