

# Large study of COPD drug finds two types of inhalers equally safe and effective

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An international study led by a Johns Hopkins pulmonary expert finds that the drug tiotropium (marketed as the Spiriva brand), can be delivered safely and effectively to people with chronic obstructive pulmonary disease (COPD) in both "mist" and traditional "dry powder" inhalers.

The new Respimat inhaler, which delivers the drug in a mist form, is approved for use in Europe but not in the United States. The traditional inhaler, known as a HandiHaler, uses a [dry powder](#) form of the drug and is widely used in the U.S.

The study comparing the two [drug-delivery systems](#) was a randomized, double-blind, prospective trial conducted at 1,200 sites in 50 countries with more than 17,000 COPD patients. Results of the study are described in an article in the *New England Journal of Medicine* on Sept. 8, 2013, and are scheduled to be presented the same day at the European Respiratory Society meeting in Barcelona, Spain, by Robert Wise, M.D., professor of medicine at the Johns Hopkins University School of Medicine.

"This was a much-awaited study, because previous, smaller studies had raised the question of whether there was an increased risk of death with the newer tiotropium device, says Wise, who is the lead author of the study. "We needed a very large trial to answer the question."

The researchers randomly assigned participants to one of three groups.

Two different doses of the drug were studied among those who used the new Respimat inhaler.

"Our study found that the safety profile of tiotropium delivered with the Respimat system, in either a dose of 5 micrograms or 2.5 micrograms, was similar to the traditional dose of the drug that is in wide use today delivered with the HandiHaler. In other words, there was no significant difference in the incidence of major cardiovascular events or risk of death among the three groups studied," Wise says.

Wise says the researchers also found that the risk of a first COPD exacerbation, defined as worsening of two or more major respiratory symptoms for at least three days, was no different when comparing the two devices or the different doses of the drug.

Tiotropium is a long-acting inhaled bronchodilator that improves lung function, quality of life and exercise endurance in patients with COPD. Patients were recruited for the study from May, 2010, through April, 2011, and followed for an average of 2.3 years. The mean age of the participants was 65, and 71 percent of the patients were men. Patients in the three groups—those who used the dry powder and those who used either 5 or 2.5 micrograms of the mist—had similar COPD severity. A substantial number of patients with a history of heart disease were included in all three arms of the study.

Death from any cause during the follow-up period occurred in 7.7 percent of patients in the lower-dose Respimat group, 7.4 percent of those in the higher-dose Respimat group and 7.7 percent among those patients using the HandiHaler.

COPD is a progressive lung disease that blocks air flow and makes it difficult to breathe. There are two forms of COPD—emphysema and chronic bronchitis. According to the National Heart Lung and Blood

Institute, COPD is the third leading cause of death in the U.S. and a major cause of disability. It is often caused by smoking and also can result from long-term exposure to air pollution or chemical fumes.

There is no cure for COPD, but inhaled medications can delay exacerbations of the disease and improve quality of life.

Provided by Johns Hopkins University School of Medicine

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