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## Cardiovascular function in patients with COPD

This is a summary of a clinical study in chronic obstructive pulmonary disease (COPD). It describes how researchers did the study and what the results were. We have written this summary for the general public.

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Thank you for taking part in this study. By taking part in this study, you helped researchers answer important questions about the combination of tiotropium and olodaterol and the treatment of COPD.

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### What was this study about?

COPD is a disease that makes it difficult to breathe. Patients with COPD have an increased risk of having cardiovascular diseases. Researchers compared 2 different treatments for COPD. They contrasted how the 2 treatments helped heart function in patients with COPD.



### Why was this study needed?

The combination of the medicines tiotropium and olodaterol is used to treat COPD. But it is not known whether taking these medicines improves heart function. This study was needed to find how these medicines affect the heart.



### Which medicines were studied?

Tiotropium and olodaterol are 2 different medicines. They are used to treat COPD. Tiotropium and olodaterol both help to open the airways. Taking both medicines together opens the airways more than taking either medicine alone. The combination of tiotropium and olodaterol (tiotropium+olodaterol) comes as a solution that needs to be inhaled. Patients take the medicine with a special inhaler called the Respimat®.

Fluticasone and salmeterol are 2 different medicines that are also used to treat COPD. The combination of fluticasone and salmeterol (fluticasone+salmeterol) works to open the airways but in a different way from tiotropium+olodaterol. Fluticasone+salmeterol comes as a dry powder that needs to be inhaled. Patients take the medicine with a special inhaler called the Accuhaler®.



## Who took part in this study?

The study included patients with COPD. The patients had no signs of cardiovascular disease. Patients could take part in the study if they had a history of smoking or were current smokers.

Overall, 76 patients took part in the study. This included 45 men and 31 women. The average age was 62 years. The youngest patient was 48 years old. The oldest patient was 74 years old. All patients were from Germany.



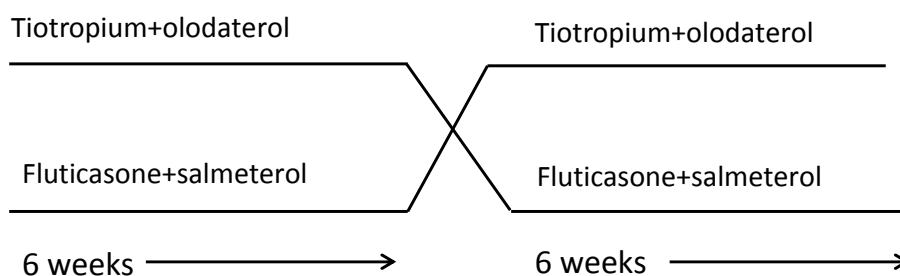
## How was this study done?

Patients took both types of treatment (tiotropium+olodaterol and fluticasone+salmeterol) for 6 weeks each. The patients were divided into 2 groups by chance. The patients did not know which treatment they were taking first or second. The doctors did not know either.

One group of patients started by taking tiotropium+olodaterol from the Respimat inhaler and placebo from the Accuhaler inhaler for 6 weeks. Then they switched to take fluticasone+salmeterol from the Accuhaler inhaler and placebo from the Respimat inhaler for 6 weeks. The placebo in each inhaler was an inactive substance that looked like the medicines.

The other group of patients started by taking fluticasone+salmeterol from the Accuhaler inhaler and placebo from the Respimat inhaler for 6 weeks. Then they switched to take tiotropium+olodaterol from the Respimat inhaler and placebo from the Accuhaler inhaler for 6 weeks.

This is shown in the picture below.



During treatment, all patients inhaled 2 puffs from the Respimat inhaler and then 1 puff from the Accuhaler inhaler each morning. They also inhaled 1 puff from the Accuhaler each evening. Each patient's Respimat inhaler had 5 µg (micrograms) tiotropium and 5 µg olodaterol, or placebo. Each patient's Accuhaler inhaler had 500 µg fluticasone propionate and 50 µg salmeterol, or placebo.

Doctors wanted to find out which treatment helped with the patients' heart function the most. They did this by looking at special images of the patients' hearts. The images are called magnetic resonance images. With these images, the researchers can find out how well the heart pumps. A measurement called LVEDVI tells the researchers how much blood the heart can pump out.

Patients visited their doctors regularly. During the visits, the doctors collected information on each patient's health.



### What were the results of this study?

Researchers found that both treatments improved the function of the heart. When patients took tiotropium+olodaterol, LVEDVI increased by an average 2.317 mL (millilitres) per square meter of body surface area. When patients took fluticasone+salmeterol, LVEDVI increased by an average 2.855 mL per square meter of body surface area. The difference between the two treatments was not meaningful.



### Were there any unwanted effects?

Unwanted effects are any health problems that the doctors thought were caused by the study medicines. In this study, no patients had unwanted effects while taking tiotropium+olodaterol. 4 out of 70 patients (6%) had unwanted effects while taking fluticasone+salmeterol. These unwanted effects were yeast infection of the mouth and throat (oral candidiasis and oropharyngeal candidiasis), voice problems (dysphonia), and dry mouth. None of the unwanted effects were serious.



### Are there additional studies?

If researchers do additional clinical studies with tiotropium and olodaterol, you will find them on the websites listed in the next section. To search for these studies, use the following names: tiotropium and olodaterol.

No additional studies are currently planned for the patients with COPD who took part in this study with tiotropium and olodaterol.



## Where can I find more information about this study?

You can find the scientific summaries of the study results at these websites:

1. Go to <http://www.trials.boehringer-ingelheim.com/> and search for the study number 1237.36.
2. Go to [www.clinicaltrialsregister.eu/ctr-search](http://www.clinicaltrialsregister.eu/ctr-search) and search for the EudraCT number 2015-002641-66.
3. Go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and search for the NCT number NCT03055988.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'An exploratory, randomised, double-blind, double-dummy, active-controlled, two period cross-over study to investigate the effect of 6 weeks treatment of orally inhaled tiotropium + olodaterol fixed dose combination (FDC) delivered by the Respimat® Inhaler with fluticasone propionate + salmeterol FDC delivered by the Accuhaler® Inhaler, on left ventricular function and arterial stiffness in patients with Chronic Obstructive Pulmonary Disease (COPD)'.

This was a Phase IV study. This study started in April 2017 and finished in March 2018.

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### Important notice

This summary shows only the results from one study and may not represent all of the knowledge about the medicine studied. Usually, more than one study is carried out in order to find out how well a medicine works and the side effects of the medicine. Other studies may have different results.

You should not change your therapy based on the results of this study without first talking to your treating physician. Always consult your treating physician about your specific therapy.

Boehringer Ingelheim has provided this lay summary in accordance with European Union transparency obligations.

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