A study to test the combination of tiotropium and olodaterol using the Respimat® inhaler in people with chronic obstructive pulmonary disease (COPD) who have different abilities to inhale

Boehringer Ingelheim

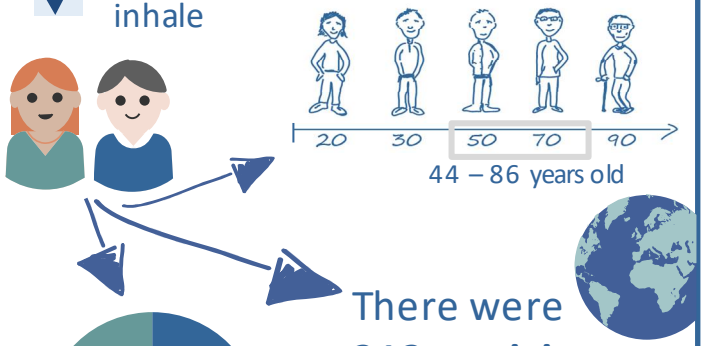
Chronic **O**bstructive **P**ulmonary **D**isease is a disease of the lung that makes breathing difficult.

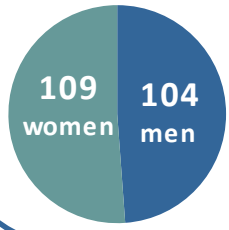
This **STUDY** was done to find out:

Does the combination of two medicines called **tiotropium** and **olodaterol** help people with **COPD**, who have different abilities to inhale forcefully from an inhaler?

Participants...

had COPD and different abilities to inhale





There were **213 participants** from the **United States** and **Germany.**

Each day, participants inhaled 2 puffs of:

Respimat®

2.5 µg tiotropium and 2.5 µg olodaterol

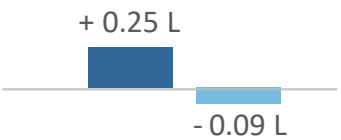
or

placebo, *which didn't contain any medicine*

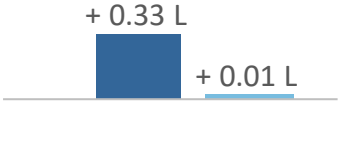
2 participants taking tiotropium and olodaterol and **2** participants taking placebo had **unwanted effects.**

RESULTS

Change in lung function for participants who had **difficulty** breathing in forcefully from an inhaler



Change in lung function for participants who had **no difficulty** breathing in forcefully from an inhaler



L = Liter

Tiotropium + olodaterol
Placebo

The combination of tiotropium and olodaterol **worked well** in both people who had difficulty breathing in forcefully from an inhaler and those without difficulty.

Study: 1237-0095

A study to test the combination of tiotropium and olodaterol using the Respimat® inhaler in people with chronic obstructive pulmonary disease (COPD) who have different abilities to inhale

This is a summary of results from 1 clinical study.

We thank all study participants. You helped us to answer important questions about the combination of tiotropium and olodaterol and the treatment of COPD.

What was this study about?

This study tested a combination of two medicines tiotropium and olodaterol. We wanted to check whether the combination helps people with COPD who have difficulty breathing in forcefully from an inhaler as well as those without difficulty. COPD is a disease that makes it difficult to breathe. Tiotropium and olodaterol are used to treat people with COPD. People take the combination of tiotropium and olodaterol by inhaling puffs of medicine through a device called the Respimat® inhaler.

Who took part in this study?

Adults with COPD aged 40 years or older, and who had difficulty breathing in forcefully from an inhaler as well as those without difficulty could participate in this study.

Overall, 213 people took part in this study. There were 104 men and 109 women. The average age was 65 years. The youngest participant was 44 years old, and the oldest participant was 86 years old. About 50% of the participants had difficulty breathing in forcefully from an inhaler and the other 50% did not have difficulty.

The study took place in the United States and Germany. 154 participants were in the United States and 59 participants were in Germany.

How was this study done?

The participants were divided into 2 groups of almost equal size.

The groups were:

- Tiotropium and olodaterol group: participants inhaled 2 puffs in the morning from an inhaler. Each puff contained 2.5 micrograms of tiotropium and 2.5 micrograms of olodaterol.
- Placebo group: participants inhaled 2 puffs of placebo each day

Every participant had an equal chance of being in the tiotropium and olodaterol group or the placebo group. The participants and doctors did not know whether the participants were in the tiotropium and olodaterol group or in the placebo group. To inhale the medicines, participants used the Respimat® inhaler.

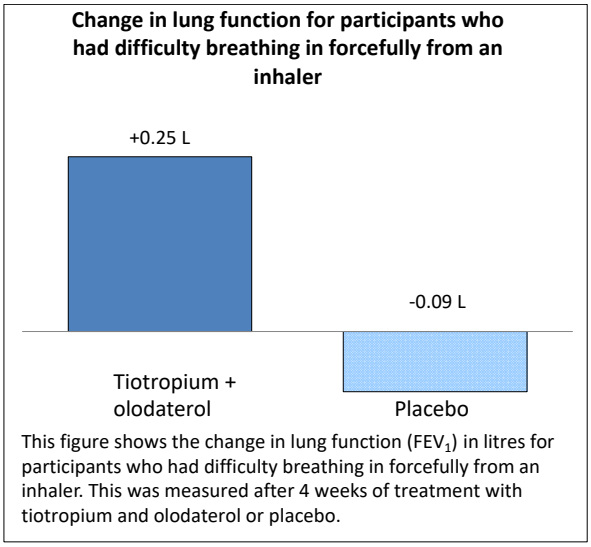
The Respimat® inhaler with placebo looked like the Respimat® inhaler with tiotropium and olodaterol, but it did not contain any medicine. We compared tiotropium and olodaterol with placebo to see how well tiotropium and olodaterol work.

Participants used the inhalers with the study treatment for 4 weeks.

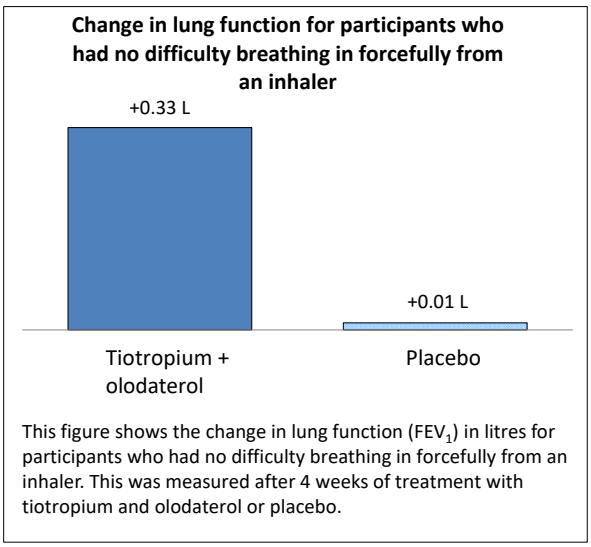
Participants visited their doctors regularly. During these visits, the doctors collected information about the participants' health and checked participants' lung function. We used forced expiratory volume in 1 second (FEV_1) to measure lung function. FEV_1 measures the amount of air that a person can forcefully blow out in 1 second after taking a deep breath. We analysed the results separately for participants who had difficulty breathing in forcefully from an inhaler and for those without difficulty.

What were the results of this study?

We checked how much the participants' lung function changed after taking the combination of tiotropium and olodaterol or placebo for 4 weeks. We found that participants who took tiotropium and olodaterol had improved lung function compared to those who took placebo. The combination of tiotropium and olodaterol worked well in both people who had difficulty breathing in forcefully from an inhaler as well as those without difficulty. The results are shown in the following figures.



This figure shows the change in lung function (FEV_1) in litres for participants who had difficulty breathing in forcefully from an inhaler. This was measured after 4 weeks of treatment with tiotropium and olodaterol or placebo.



This figure shows the change in lung function (FEV_1) in litres for participants who had no difficulty breathing in forcefully from an inhaler. This was measured after 4 weeks of treatment with tiotropium and olodaterol or placebo.

Did participants have any unwanted effects?

Yes, 2 participants taking tiotropium and olodaterol and 2 participants taking placebo had unwanted effects. Unwanted effects are health problems that the doctors think were caused by tiotropium and olodaterol or placebo. The unwanted effects were COPD, stuffed or runny nose (rhinitis), cough, dry mouth, and dry tongue.

None of the unwanted effects were serious. This means that the unwanted effects did not lead to a hospital stay, that they were not life-threatening, and that they did not lead to a disability.

Where can I find more information about this study?

You can find further information about this study at these websites:

1. Go to http://www.mystudywindow.com and search for the study number 1237-0095.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2019-001719-21.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT04223843.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A randomised, double-blind, placebo-controlled, multi-centre, parallel-group study to compare the efficacy of inhaled tiotropium + olodaterol, fixed dose combination (5 µg/5 µg) vs. placebo delivered by Respimat® inhaler in patients with moderate to severe COPD, stratified by peak inspiratory flow rate [TRONARTO]'.

This was a Phase 4 study. This study started in January 2020 and finished in September 2020.

Are there additional studies?

If we do more clinical studies with tiotropium and olodaterol, you will find them on the websites listed above. To search for these studies, use the words tiotropium and olodaterol.

Important notice

This lay summary is provided as part of Boehringer Ingelheim's commitment to publicly share clinical study results.

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

This lay summary may include uses, formulations, or treatment regimens for the medicine studied that may be approved or not approved in your country. This lay summary is not intended to promote any product or indication, to guide treatment decisions, or to replace the advice of a healthcare professional.

You should not change your therapy based on the results of this study. Always consult with your treating physician about your therapy.