This is a summary of a clinical study for children with asthma.

This study tested whether a medicine called Tiotropium Respimat® is helpful for children with asthma.

Enjoy reading it!


BACKGROUND
Come on, we'll be late for school!
What's that you've got?
What?
That!
That's my trumpet, for my band!
No, that!
Oh, that's my inhaler, for my asthma!
Asthma?
You know, when it's hard to breathe.
Like when I hold my breath?
No, worse. It makes me cough a lot, sometimes.
I've even had to miss school because it makes me sick.
What about the doctors? Can't they help?


They try to!
Last year I helped the doctors test a medicine for it.
It's called tiotropium and it helps open up the airways in my lungs.
Lungs - I remember learning about lungs in science class!
Yes, they help us breathe in and out, but mine need extra help sometimes.
That's why the doctors asked me to help test tiotropium in a study.
They wanted to see how well different doses work.
A study? What does that mean?


HOW WAS THIS STUDY DONE?
The doctors explained everything to me before we started.
There were a lot of children put into different groups.
Two groups took tiotropium for almost a whole year.
A whole year!
Almost, and another group took something called a placebo.
Is that another medicine?
No, it's like a pretend-medicine.
It looked like the tiotropium inhaler but there was no medicine in it.
So how did the doctors know if the medicines work or not?
Well, I took special breathing tests.
Tests?


Yes, they had a special machine.
I had to blow out as hard and as fast as I could!
It was like blowing into my trumpet!
That sounds kind of fun!
So then what happened?


WHAT WERE THE RESULTS OF THE STUDY?
There were 401 girls and boys from 6 to 11 years all over the world testing tiotropium.
401 children blowing trumpets! Wow!
And at the end of the study the doctors looked at the results.
The kids who took tiotropium could blow out more air than the kids who took the placebo.
Hmm. But I've heard that medicines can sometimes cause health problems.
Did that happen to any of the kids?
You mean unwanted effects?
That's what the doctors call health problems caused by medicines.


The children who took the placebo had unwanted effects.
One had a cough. The other had dry skin.
What about the kids who took tiotropium?
No, none of the children who took tiotropium had unwanted effects.
Hey, we'll be late for school! I'll race you! I'll be first!
Not a chance!
SCHOOL

Efficacy and Safety of 2 Doses of Tiotropium Respimat® Compared to Placebo in Children with Moderate Persistent Asthma

This is a summary of a clinical study in asthma. This summary describes the results of the study.

We thank all children who took part in this study. You helped to answer important questions about tiotropium and the treatment of asthma.

What was this study about?

Researchers wanted to find out if a medicine called tiotropium helps children with asthma.

Why was this study needed?

Asthma is a disease that causes the airways in lungs to become narrow. This can lead to coughing, wheezing, and shortness of breath. Asthma in children can cause school absences, visits to the emergency department, or stays in hospital. Tiotropium is a medicine that can help treat asthma. It helps to widen the airways in the lungs.

There are some other medicines available to treat asthma in children. Some children with asthma need to take more than one medicine. In this study, researchers needed to find out whether tiotropium can help children with asthma if they take it in addition to their usual asthma medicine.

Which medicines were studied?

Researchers studied the medicine tiotropium. Tiotropium is used to treat asthma and another lung disease called chronic obstructive pulmonary disease. It helps to open the airways and keeps them open all day long. This makes it easier to breathe. Tiotropium comes as a solution that needs to be inhaled. The study tested 2 different doses of tiotropium. Some children in the study took placebo instead of tiotropium. The placebo looked like tiotropium but did not contain any medicine. The children in the study used a special inhaler called the Respimat® to take tiotropium or placebo.

Who took part in this study?

Children with moderate persistent asthma could take part in the study. They had to be aged between 6 and 11 years old. A total of 401 children took part. There were 264 boys (65.8%) and 137 girls (34.2%). Their average age was 8.9 years. All of the children were already taking other medicines for their asthma. The countries that the study was done in are listed below.

Europe	Asia
Bulgaria, Germany, Hungary, Latvia, Lithuania, Portugal, Romania, Russia, Sweden, Ukraine, and United Kingdom	Korea
North America	**Central America**
United States	Guatemala

How was this study done?

The children were divided into 3 groups. One group of children received tiotropium at a dose of 2.5 µg per day. Another group received tiotropium at a dose of 5 µg per day. The third group of children received placebo. Every child in the study had an equal chance of being in any of the 3 groups. The children and their parents did not know which treatment the child was taking. The doctors did not know either.

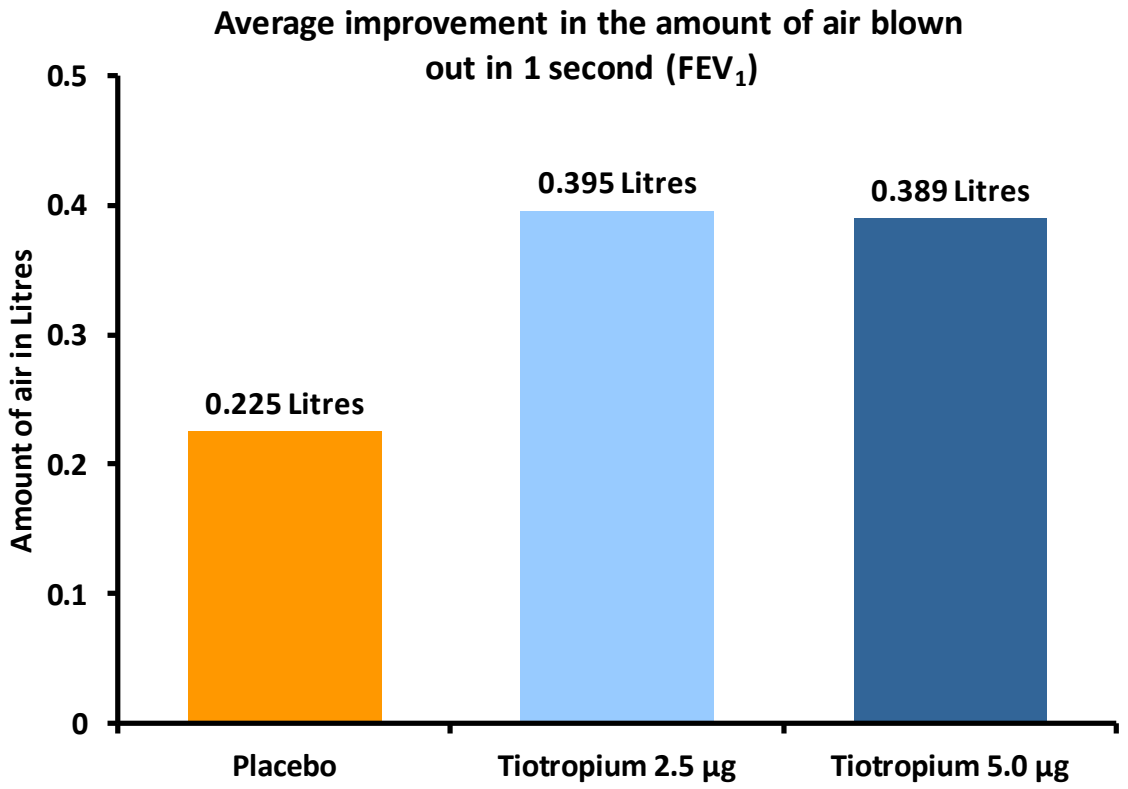
The children took tiotropium or placebo for 48 weeks. They also continued with their usual asthma medicine.

Researchers wanted to know if children who took tiotropium had improved lung function after 24 weeks. To look at lung function, the researchers measured how much air the children could blow out of their lungs in 1 second after taking a deep breath. They compared the children who took tiotropium to the children who took placebo.

The children visited the doctors regularly. During these visits, the doctors collected information about the child's health.

What were the results of this study?

The results of the study showed that taking tiotropium improved the lung function of the children. The children who took tiotropium could blow out more air after 24 weeks than they could before they started to take tiotropium. This improvement in lung function was larger for children who took tiotropium than for children who took placebo. The results of the study are shown in the picture below.



Children taking tiotropium 2.5 µg or 5.0 µg had larger improvements in the amount of air they could breathe out (FEV_1) after 24 weeks than children taking placebo.

Did patients have any unwanted effects?

Yes, children in the placebo group had unwanted effects. Unwanted effects are health problems that the doctors think were caused by the study medicines. In this study, 2 out of the 401 children who took part had unwanted effects. Both of these children were in the placebo group. The unwanted effects in these children were cough and dry skin. No children who took tiotropium had unwanted effects.

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 205.445.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2011-001758-26
3. Go to www.clinicaltrials.gov and search for the NCT number NCT01634139.

Boehringer Ingelheim sponsored this study.

The full title of the study is: A randomised, double-blind, placebo-controlled, parallel-group trial to evaluate efficacy and safety of tiotropium inhalation solution (2.5 µg and 5 µg) delivered via Respimat® inhaler once daily in the evening over 48 weeks in children (6 to 11 years old) with moderate persistent asthma.

This was a Phase 3 study. This study started in August 2012 and finished in December 2015.

Are there additional studies?

If researchers do additional clinical studies with tiotropium, you will find them on the websites listed above. To search for these studies, use the following names: Tiotropium, Tiotropium Bromide.

No additional studies are currently planned for the children with asthma who took part in this study with tiotropium.

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.