Clinical Trial RESULTS

AstraZeneca

Research Sponsor:	AstraZeneca
Drugs Studied:	budesonide/formoterol (Symbicort®)
National Clinical Trial #:	NCT02533505
Protocol #:	D589CC00014
Study Date:	August 2015 to August 2016
Short Study Title:	A study of participants with moderate to severe COPD to see if a dose of Symbicort® can help improve heart function.

Thank you!

As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and discover new medical treatments.

Thank you for taking part in the clinical study for the drug Symbicort®. This is an approved drug that is taken in an inhaler to treat asthma and chronic obstructive pulmonary disease, also called COPD. Symbicort is a combination of 2 drugs, budesonide and formoterol. You and all of the participants helped researchers learn if a single dose of Symbicort can help improve heart function. Researchers wanted to test this dose to see how much oxygen the body uses at rest when a person with COPD takes Symbicort. Researchers also wanted to see if this dose causes medical problems.

AstraZeneca, the sponsor of this study, thanks you for your help and thinks it is important for you to know the results of your study. An independent non-profit organization called CISCRP prepared this summary of the study results for you with the help of a medical writing organization. We hope it helps you understand and feel proud of your important role in medical research. If you have questions about the results, please speak with the doctor or staff at your study site.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

What's happened since my study ended?

Your study started in August 2015 and ended in August 2016. It included 51 participants at 5 study sites in the United States. When the study ended, the sponsor reviewed the data and created a report of the results. This is a summary of that report.

Why was the research needed?

Researchers were interested in better understanding the benefits of Symbicort, a medicine used to treat COPD. COPD is a lung disease that causes inflammation and narrowing of the airways. This may cause air to be trapped in the lungs. This is known as "hyperinflation" and can make it harder to take in each breath.

In this study, researchers wanted to find out how much oxygen the body uses at rest when a participant's hyperinflation improved after taking a dose of Symbicort. If participants' hyperinflation got any better, Symbicort may have helped their hearts work better and may have helped change the amount of oxygen their bodies used while at rest.

Researchers compared a single dose, or 2 puffs, of Symbicort with a placebo. A placebo looks like the study drug but contains no real medicine. Researchers use placebos in studies to compare the results for participants who take study drugs with the results for participants who take no medicine at all. Researchers wanted to know:

- Was there a link between Symbicort and the amount of oxygen used throughout the body compared to a placebo?
- Was there a link between Symbicort and a change in the strain on the heart compared to a placebo?
- What medical problems did participants have after they took Symbicort?

What kind of study was this?

Your study was a "double-blind" study. This means that none of the participants, researchers, or staff knew what treatment each participant took. Some studies are done this way because knowing what treatment each participant is taking can affect the results of the study. This way, the results are looked at fairly. In this study, everyone took the study drug and a placebo.

Your study included participants with moderate to severe COPD who were 45 to 79 years old.

What happened during the study?

You and other participants were in the study for up to 6 weeks.

All 51 participants visited their study site 4 times in 4 weeks, and took either Symbicort or the placebo during these visits. The visits were 1 week apart. Participants did not stay overnight at the study site during these 4 visits.

The study had 2 groups. Participants in both groups took Symbicort and placebo in 1 of 2 treatment cycles:

- Symbicort ➡ Placebo ➡ Symbicort ➡ Placebo
- Placebo ➡ Symbicort ➡ Placebo ➡ Symbicort

The order participants took Symbicort and the placebo was determined by chance, like rolling dice.

One total dose of Symbicort for each participant contained 320 micrograms, or µg, of budesonide and 9 µg of formoterol. A µg is a widely accepted scientific unit of measurement.

During the study, doctors checked each participant's blood pressure, pulse rate, and temperature. They also tested participants' blood and urine to make sure the participants were still healthy, and asked participants how they were feeling. Finally, study doctors checked participants' hearts using an electrocardiogram, or ECG.

In between treatments, each group had a two day "washout period". During the washout periods, participants did not take any drugs, except for their rescue inhaler if needed. This helped get rid of any effects from previous treatments.

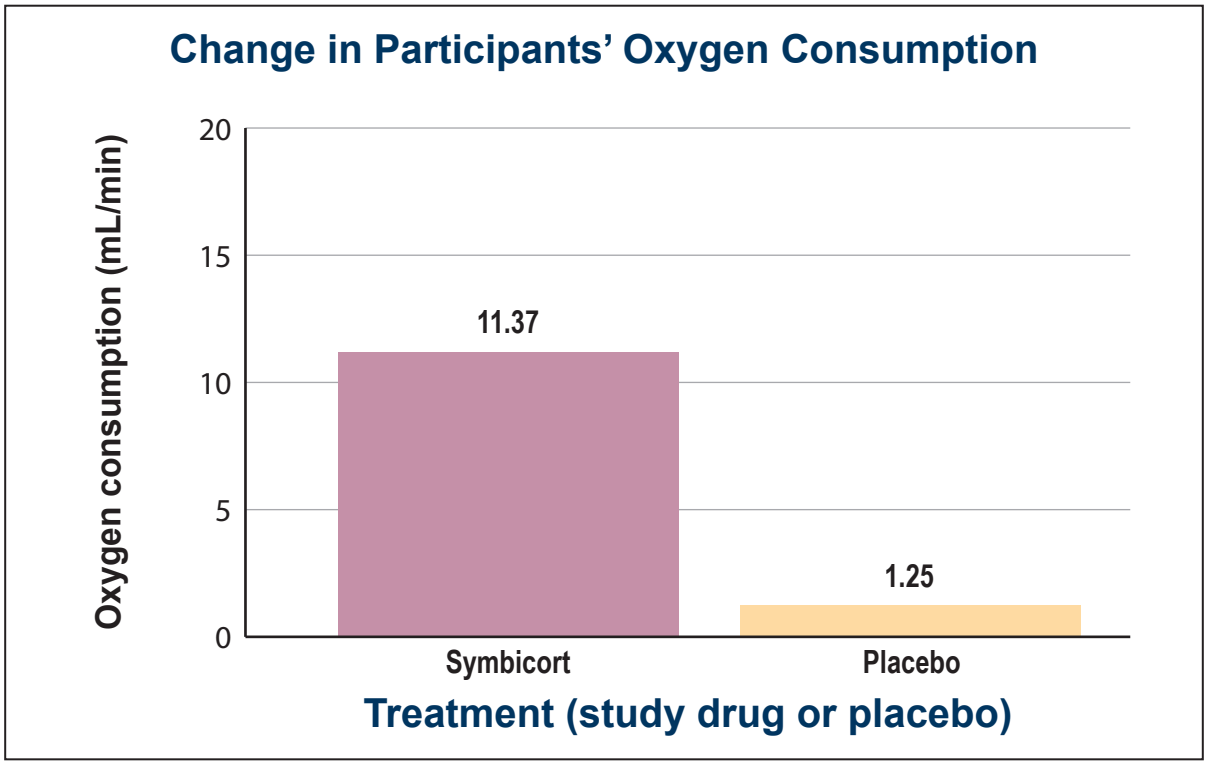
What were the study results?

Was there a link between Symbicort and the amount of oxygen used throughout the body compared to a placebo?

Researchers looked at the amount of oxygen participants' bodies used to answer this question.

Researchers compared participants' oxygen consumption before taking a dose of Symbicort or placebo to their oxygen consumption after their dose. The figure on the next page shows this change in participants' oxygen consumption in milliliters per minute, or mL/min. This is a widely accepted scientific unit of measurement.

Researchers found that the increase in oxygen consumption while taking Symbicort was 10.1 mL/min higher than the increase in oxygen consumption while taking a placebo. Participants' oxygen consumption after taking Symbicort increased by 11.37 mL/min compared to their oxygen consumption before taking Symbicort. Participants' oxygen consumption after taking a placebo increased by 1.25 mL/min compared to their oxygen consumption before taking a placebo.



Was there a link between Symbicort and a change in the strain on the heart compared to a placebo?

To answer this, researchers looked at participants' heart function, lung function, and difficulty breathing.

Heart function

It's important for you to know that Symbicort was shown to change the amount of oxygen used by participants' bodies. Researchers are still trying to understand if the increase caused by Symbicort in this study improved heart function. To test heart function, researchers looked at the amount of oxygen the blood takes in with every heartbeat. This is called the "oxygen pulse".

In this study, participants' oxygen pulse increased after taking Symbicort. This result may mean that heart function improved, but the amount of this increase was not large enough to know this for sure. Researchers are still trying to understand the significance of this result.

Lung function

It is already known that Symbicort causes an increase in lung function. In this study, there was an increase in the amount of air participants exhaled after taking Symbicort.

To test lung function, researchers measured how much air participants could exhale. After treatment, researchers found that the increase in the amount of air exhaled by the lungs was greater for participants who took Symbicort than for those who took the placebo.

Difficulty breathing
To test how difficult it was for participants to breathe, researchers asked participants to rate their shortness of breath during activities. After treatment, researchers found that participants who took Symbicort reported a greater decrease in shortness of breath than those who took a placebo.

What medical problems did participants have during the study?

A lot of research is needed to know whether a drug causes a medical problem, so researchers keep track of all medical problems that participants had during the study. These medical problems are called "adverse events". They may or may not be caused by the study drug.

How many participants had medical problems in the study?

The table below shows how many participants in the study developed medical problems. Two participants stopped taking the study drug because of a medical problem.

	Symbicort (51 participants)	Placebo (51 participants)
How many participants developed medical problems?	13 (25.5%)	11 (21.6%)

How many participants developed serious medical problems?

A medical problem is considered serious when it is life threatening, causes lasting problems, or needs hospital care. In this study, no participants developed serious medical problems while taking Symbicort, and 1 participant (2.0%) developed a serious medical problem of pneumonia while taking a placebo. No participants died during this study, and no new safety concerns were raised.

What were the most common medical problems in the study?

The table below shows the most common medical problems that happened in at least 3.0% of participants in the study.

	Symbicort (51 participants)	Placebo (51 participants)
Back pain	2 (3.9%)	0
Common cold	2 (3.9%)	0
COPD	0	3 (5.9%)
Shortness of breath	2 (3.9%)	2 (3.9%)

Where can I learn more about the study?

If you have questions about the results, please speak with the doctor or staff at your study site. You can find more information about your study online at www.clinicaltrials.gov/show/results/NCT02533505.

Official study title: Phase IV O2 Consumption Study in COPD Participants

The phone number for the AstraZeneca Information Center is 1-877-240-9479.

The results presented here are for a single study. Other studies may provide new information or different results. You should not make changes to your therapy based on the results of a single study without first consulting your healthcare professional.

Thank you

It is said that the greatest gift is one which is given anonymously, giving when you do not know whether you will get direct personal benefit.

This is the gift that you have given by taking part in a clinical trial. It is a brave and selfless act, one that advances medical knowledge and benefits public health.

Thank you for the gift of your participation in clinical research.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting participants for clinical trials, nor is it involved in conducting clinical trials.

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