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IRB Approved at the
Protocol Level
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vathos

Do you have asthma?

If your symptoms are not fully controlled on your current treatment, the VATHOS study may be an option.

See if You Qualify

Understanding Asthma

Asthma is a condition that causes your airways to become swollen and inflamed. The inflammation makes your airways narrower and can cause shortness of breath, coughing, wheezing or whistling when you breathe, and a tight feeling in your chest.

Over time, the inflammation from asthma can cause the walls of your airways to thicken. This means the space inside your airways gets narrower, which can make it even more difficult to breathe. This is more likely to happen if your symptoms are not well-controlled.

Certain medicines can be used to help keep asthma symptoms under control. Devices called inhalers allow you to breathe in, or inhale these medicine(s) and deliver them directly to the airways where they are needed. The three main types of preventative long-term asthma medications are inhaled corticosteroids (ICS), long-acting beta agonists (LABA), and biologics.

About the VATHOS Study

The VATHOS study is evaluating if a new investigational inhaler called Budesonide and Formoterol Fumarate (BFF) metered dose inhaler (MDI) may provide benefit for people whose asthma symptoms are not fully controlled using their current inhaler treatment. Researchers will compare BFF MDI against BD MDI (a similar investigational inhaler) and Symbicort® Turbuhaler® (an approved treatment for asthma) to see if it is better, worse, or the same at controlling asthma symptoms. This study will also help us learn more about asthma and other associated conditions.

What Are the Study Treatments?

BFF is an investigational metered dose inhaler (MDI) that sprays a specific combination of the medicines budesonide and formoterol fumarate into the airways. Both of these medicines are already approved to treat asthma, either on their own or in combination with other medicines. The two medicines are designed to work together to reduce inflammation, relax the muscles in the airway, and help keep the airways open.

Two different dose levels of BFF will be compared against:
BD, a similar investigational MDI containing only budesonide, and Symbicort® Turbuhaler®, an approved inhaler containing budesonide and formoterol fumarate.

Why Participate?

Before a potential treatment for asthma can be approved, it must first be tested in a series of clinical trials. By choosing to volunteer for this study, you can help us learn more about how the BFF MDI works. The findings from this study may lead to better treatment options and help other people with asthma in the future.

Who Can Participate?

This study may be an option for people who:

- Are 12 to 80 years old
- Have been diagnosed with asthma for at least six months
- Have been using the same low dose of ICS or ICS/LABA (inhaled corticosteroid/long-acting beta agonist) inhaler medication every day for at least eight weeks before their first study visit

There are other requirements to join this clinical study. A study team member will help determine if this study is right for you based on all participation criteria.

What to Expect

This study is split into three periods: Screening, Treatment, and Follow-Up:

Screening (3 weeks)

The screening period will determine if this study is a good fit for you. Over the course of three weeks, participants will be asked to attend three clinic appointments for various tests and assessments, including a physical exam, lung function tests, heart tests, urine samples, and blood draws.

Treatment (24 weeks)

Participants who meet the screening criteria will enter the treatment period of the study for 24 weeks (about six months). Participants will be randomly assigned to one of four possible groups to receive one of the following treatments:

- High dose BFF MDI
- Low dose BFF MDI
- BD MDI
- Symbicort® Turbuhaler®

Neither participants nor the study doctor will know what has been assigned. During the treatment period, participants will need to use the study inhaler twice a day and attend two virtual and five in-person appointments.

Participants will also need to respond to questions and record their asthma symptoms at home in an eDiary (a handheld electronic device) and measure their lung function using a peak flow meter (a small device that you blow air into). The study team will provide the eDiary and peak flow meter and instruct participants on their use.

Follow-Up (2 weeks)

Participants will have a follow-up phone call two weeks after their last dose of the study treatment so the study team can continue to monitor their health and well-being.

Can I Participate? Answer a few questions, it'll take less than 1 min... **See if You Qualify**

A parent or guardian should answer the following questions on behalf of minors under 18.

QUESTION 1 OF 4

Are you 12 to 80 years old?

YES **NO**

QUESTION 2 OF 4

Were you diagnosed with asthma at least six months ago?

YES

NO

QUESTION 3 OF 4

Have you been using the same dose of ICS or ICS/LABA (inhaled corticosteroid/long-acting beta agonist) inhaler medication for asthma every day for at least eight weeks?

YES

NO

ICS or ICS/LABA may be known as Advair Diskus/HFA, Airduo Respiclick, Breo Ellipta, Dulera, or Symbicort.

QUESTION 4 OF 4

Are you a current smoker?

YES

NO

Smoking includes all forms of tobacco, e-cigarettes or other vaping devices, and marijuana.

We're sorry, but you are not eligible at this time...

Thank you so much for your interest in the VATHOS Study and for answering our questions. Contact your healthcare provider if you have any medical questions. Also, please consider entering your information below to be contacted about future clinical research opportunities.

First Name

Last Name

Phone Number

Email

Address

How Did You Hear About Us?

[from my primary care provider, from another doctor (specialist), from a waiting room poster, from radio or TV, from a paper advertisement, from the internet, Others]

SEND