DOES IT COST ANYTHING TO PARTICIPATE?

All study-related medical examinations, study procedures, and the study drug are provided at no cost. Compensation for study related travel expenses while taking part in this research study may also be available to those who qualify and participate.

ARE THERE ANY RISKS TO PARTICIPATING IN THIS RESEARCH STUDY?

There may be potential risks to participating in this research study. All drugs and medical procedures carry a risk of side effects. It is possible that participants may experience some discomfort or other side effects associated with the use of the study drug. The study staff at the study doctor's office will explain in detail the potential risks of participation to help you make an informed decision about your child participating.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

Your child may or may not receive any personal benefit from participating in this research study. However, new information that is received from this study may help to answer questions that medical researchers have about potential treatments for children who have dust mite allergies.

WHAT ARE THE NEXT STEPS?

If you think participating in this research study might be right for your child, please talk with your family and then to your doctor. If you wish to take the next step toward possible participation, or if you have more questions, please contact us as directed on the back of this brochure. Contacting us does not obligate you or your child to participate in this study.

For more information about this research study, please contact:

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Is your child age 5-11 allergic to dust MITES?

If so, participation in our research study may be an option for your family.

The investigational medication being studied is an immunotherapy approved for adults in the US and several other countries.

People who are allergic to dust mites can suffer from year-round symptoms. These symptoms include runny or stuffy nose, sneezing, itchy or watery eyes, and/or asthma. These symptoms are also called allergic rhinitis or allergic rhinoconjunctivitis.

Dust mite allergies are common among children and adolescents in the US. These allergies could decrease school attendance, performance, interfere with daily activities, and disrupt healthy sleep patterns.

If your child is between ages 5 and 11 and has been diagnosed with dust mite allergies for at least one year, please read the answers to the following frequently asked questions. Then, contact us as directed at the end of this brochure if you think our study may be an option for your family.

WHY IS THIS RESEARCH STUDY BEING CONDUCTED?

This research study is being conducted to see if the study drug can improve allergy symptoms in children ages 5 to 11 with sensitivity to dust mites. While dust mite allergies can be treated with antihistamines or steroids, many people's symptoms are not well-controlled by these medications.

The study drug is an immunotherapy in the form of a sublingual tablet. The tablet is taken daily and is placed under the tongue, where it dissolves quickly. Immunotherapy consists of regularly giving very small amounts of the substance that causes the allergic reaction. The goal of immunotherapy treatment is to gradually create tolerance and reduce symptoms.

WHO CAN PARTICIPATE IN THIS RESEARCH STUDY?

To qualify for this research study, potential study participants must meet the following conditions:

- Be 5 to 11 years old
- Have been diagnosed with dust mite allergies for at least 1 year
- Have allergic symptoms despite taking allergy medications in the past year

There are additional requirements for participation. The study staff will explain the complete list of requirements.

WHAT DOES THIS RESEARCH STUDY INVOLVE?

Before any study-specific procedures begin, the study staff will first give a detailed explanation of this research study and its potential risks and benefits. After receiving this information, the parent or guardian of the child participating in the study will be required to sign an informed consent form. The participant may also be asked to sign an assent form, depending on their age.

After consent has been given, the screening period of the study begins. During screening, the study staff conducts a series of study-related examinations and assessments to see if the potential participant satisfies the requirements to proceed.

If the study doctor decides that the requirements are satisfied, the baseline period of the study begins. The study staff will give the participants' parents an electronic diary (also known as an e-diary), which looks like a smart phone. The parents will use the e-diary to record their child's allergy symptoms and medications. The baseline period will consist of 3 weeks of daily e-diary entries. After the 3 weeks, the study staff will review the information from the entries and determine whether the participant qualifies to enter into the treatment period of the study.

The treatment period of the study will then begin for participants who continue to qualify. The treatment period will last approximately 52 to 57 weeks. Participants will be assigned to receive either the study drug or placebo. The placebo is a substance that looks like the study drug but has no active ingredients. The chances of receiving either the study drug or placebo are 50%, like flipping a coin.

At certain periods of time during the treatment period, the participants' parents will be required to make daily entries in the e-diary.

In total, this study will involve 7 visits to the study center and 3 telephone visits over a period of about 14 months.