RAGWEED-INDUCED SEASONAL ALLERGIES.

- Seasonal allergies occur during certain times of the year
- Ragweed pollen can cause allergic reactions; up to half of all cases of pollen-related allergic rhinitis in North America are caused by ragweeds[1]
- Symptoms may come on suddenly, start at almost any time during the ragweed season, and include runny nose, stuffy nose, sneezing, itchy nose, itchy eyes, and watery eyes
- Participation in clinical research studies is a way to help researchers develop new medication or therapy

[1] Frenz D, "Volumetric Ragweed Pollen Data for Eight Cities in the Continental United States," *Annals of Allergy, Asthma & Immunology* 82 (Jan 1999): 41–6.

WANT MORE INFORMATION?

Simply ask your doctor for more information or contact our clinic to see if your child may be eligible to participate.

CLINIC NAME:

CONTACT PERSON:

ADDRESS:

TELEPHONE NUMBER:

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ARE RAGWEED ALLERGY SYMPTOMS AFFECTING YOUR CHILD?

Your child may be able to participate in a clinical research study for an investigational oral medication that is being studied to see if it may help symptoms of ragweed allergies in children.

MERCK
Pediatric
Ragweed
STUDY

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COULD YOUR CHILD BE ELIGIBLE?

We are looking for children ages 5 to 17 to participate in a clinical research study of an investigational medication in the form of a sublingual (under the tongue) tablet. The purpose of this study is to determine if the investigational medication is safe and effective at helping the symptoms of ragweed-induced seasonal allergies in children.

Approximately 1,000 volunteers around the world will participate in this clinical research study. The investigational study medication will be provided to study participants at no charge.

There may be risks associated with participating in this clinical trial. The study doctor will explain these risks to you, and answer any of your questions.

WHAT WILL YOUR CHILD BE ASKED TO DO?

Before enrolling into the study, your child will be asked to attend a screening visit where the study team will explain requirements and answer any questions you may have. The study team will ask you questions about your child's medical history and perform a physical examination and other tests.

If your child qualifies, participation will last at least 6 months, up to 18 months from the time you sign the informed consent form (ICF) through to final contact with the study team. Study participants will receive the investigational medication or a placebo (which does not have any active medication) for a few months before the ragweed allergy season begins and throughout the season. There is an equal chance of receiving either the investigational medication or the placebo, and you will not know which has been assigned.

Your child will be given an e-diary to complete each day during the trial to monitor your child's allergy severity. Each entry should be completed in the evening before bedtime, preferably. If an entry cannot be completed for the e-diary at the regular time, it can be completed up until 9am the following day. An e-diary will be issued at Visit 2 and collected at Visit 8. Instructions on how to complete entries and e-diary findings will be reviewed with you or your child at all visits. In addition, medication approved for use in children and teens to relieve seasonal allergies (standard medication) will be provided right before the ragweed allergy season begins. If any of these medications are taken to relieve your child's allergy symptoms, this information will be reported on the e-diary. Either you or your child will keep the e-diary up-to-date.

There may be additional requirements that the study doctor will explain to you.

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WHAT YOU SHOULD KNOW ABOUT CLINICAL RESEARCH STUDIES.

Clinical research studies aim to answer specific questions about how medicines work in the volunteers who take them. You should feel fully informed about what to expect from participation in a clinical research study.

A clinical research study will usually evaluate a medicine so that researchers can learn the following:

- If the medicine actually works. For this study, that means your doctor will want to know how severe your child's allergies are while he or she takes the study medicine.
- If the medicine has side effects. Side effects are other effects that a medicine can have. Sometimes the side effects can make your child feel bad, and you may decide that you do not want him or her to take the medicine. For this study, that means that you will need to tell the doctor how your child feels when he or she takes the study medicine and if you want to stop it.

Clinical trials are typically performed in "phases." Before a medication can be tested in human subjects, testing occurs in a lab to gather data on whether the investigational medication may work to treat the disease or condition. Next, the investigational medication transitions to something called a Phase I clinical trial, which typically involves a small number of healthy subjects and is designed to test whether the investigational medication is safe and to determine what dose should be given. If the results show that the medication is safe, it will move into Phase II clinical trials, where it will be tested in patients with the disease or condition to see whether the investigational medication has any effect on the disease or condition. If the investigational medication works to treat a disease or condition, it will enter Phase III trials, which involve a large number of patients to see if it is safe and effective.

Regulations and policies have been developed to help protect the rights, safety, and well-being of people who take part in clinical research studies and to help ensure that these studies are conducted according to strict scientific and ethical principles. Before a clinical research study can begin, a review board must review and approve the study. This group is called an IRB, or institutional review board, and is comprised of doctors, scientists, and members of the community.

Participation in any clinical research study is completely voluntary, and you may withdraw your child from a clinical research study at any time for any reason. Your decision will not affect your child's routine care.

Before volunteering for a clinical trial, it is important to weigh the risks and benefits of becoming a participant. The study staff will inform you of the risks and benefits of your child's participation, as well as possible side effects. To make an informed decision, gather as much information as possible and talk to your healthcare providers about any questions.

During the study, you and your child will work with a research team that may include study doctors, study nurses, and other research staff. Without your help and the commitment of the study team, the development of new medication choices would not be possible.

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