

Needed: Children, Teens and Adults 12 Years or Older Who Have Severe Asthma

What is the purpose of this study?

This is a research study to learn more about the safety and effectiveness of a new drug, called mepolizumab, in treating asthma.

Researchers also want to know how the body reacts to the drug and if there is a change in the number of asthma attacks a person has while taking mepolizumab.

Who can participate?

Children, teens and adults 12 years old and older who been diagnosed with asthma
AND:

- Have been using a steroid inhaler for 12 months
- Have been in the hospital or emergency room at least 2 times because of their asthma

What is involved?

You or your child will take part in this research study for about 38 weeks and complete 11 study visits.

During the study, you or your child will be “randomized” into 1 of 2 groups and receive either a dose of the study medication or a placebo (a substance that looks like study medication but has no active ingredient in it). Randomization means that participants are put into the groups by chance, like flipping a coin. No one will know which group you or your child is in, including the researcher.

You or your child will be given the study medication or placebo every 4 weeks by an IV in one arm (a soft needle in the vein to give the drug) and a shot in the other arm. **It's important that you or your child keep taking your usual asthma medicines during this study.**

You will also complete health-assessments, including:

- Review of medical and medication history
- Physical and nasal exams (including height, vital signs, blood pressure, heart rate, respiration rate, oral temperature and body weight)

- Electrocardiogram (called an ECG or EKG) to measure the heart's electrical activity (heartbeat or heart rhythm)
- Reversibility breathing tests to measure how the lungs are working before and after taking asthma rescue medication
- Questionnaires about your asthma and health status
- Electronic diary to measure breathing on a daily basis
- Blood and urine tests

A detailed list of procedures will be provided to anyone interested in knowing more about this study.

What are the benefits?

You or your child may or may not receive a direct medical benefit from participating in this study. However, the information learned from this study may benefit other patients with asthma in the future.

Will I get all the facts about the study?

If interested in participating, you, as either a participant or parent of a participant, will be given a consent form that explains all of the details of the study. The form covers all of the procedures, risks, benefits, pay, whom to contact with questions or concerns and more. A member of the study staff will review the consent form with you and will be sure that all of your questions are answered.

What are the risks and discomforts of this study?

You or your child may experience side effects associated with your participation in this study. Any discomforts or risks will be discussed with you if you are interested in learning more about the study.

Do participants receive pay, compensation or reimbursement?

Participants may be paid up to \$565 for completing all study visits.

Who should I contact for more information?

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