



This sheet gives information on a research study funded by the National Heart, Lung, and Blood Institute. This study is being done at up to 20 medical centers in the U.S., Canada, and Europe to compare two drugs (atenolol and losartan), to see which one is better at slowing the rate of enlargement of the aorta (main blood vessel from the heart to the body) in children and young adults with Marfan syndrome.

What is Atenolol?

Atenolol is a drug that is commonly used to treat high blood pressure and is also used in children with Marfan syndrome. Studies have shown that atenolol slows the rate of aortic root enlargement in people with Marfan syndrome but does not prevent the need for surgery on the aorta.

What is Losartan?

Losartan is a drug that is commonly used to treat high blood pressure, and is approved for use in children 6 years and older. Studies have shown that losartan can prevent aortic root enlargement in mice with Marfan syndrome. Losartan has not been studied in people with Marfan syndrome.

How can you join the study?

You must have certain traits of Marfan syndrome and you must sign a consent form before you may take part in this study. If you decide to join, we will read and make notes about information from your medical chart to get background information about your heart problems, any other medical problems you have, and how the heart condition has been treated. We will talk with you about your medical history, examine you, and review your previous echocardiograms (pictures, taken by sound waves, of your heart and blood vessels).

What medication will you be taking?

You will take either atenolol or losartan. You will not know what medicine you are taking.

What tests are required during the study?

The study will last 3 years. There are five major study visits for testing—at the beginning, and then again at 6, 12, 24, and 36 months after the first visit. Some of the visits and/or tests that are planned may be part of regularly scheduled visits to your doctor. There may be several more visits in the first few months of the study so that we can find out the best dose of study drug for you.

Taking part in this study involves:

Measurement of growth: You will have your weight, height, arm length, and leg length measured at each visit.

Questionnaires: We will ask you some questions at each visit to find out if you have side effects from the study medication.

Echocardiograms: An echocardiogram is a painless test using sound waves to take a picture of your heart. You may have as many as five echocardiograms for the study, one at each of the major study visits. For this test, you will need to lie quietly on a table for about 30 minutes.

Blood Tests: You will have blood taken twice.

24-hour Electrocardiogram (Holter monitor): A Holter monitor is a painless test that records your heart rhythm. You will wear a small box about the size of a pager during your normal activities for 24 hours. You will have a Holter before you start the study medicine, several times in the first few months to help us figure out the correct dose of study medication, and again at each study visit (6, 12, 24, and 36 months).

Are there any costs?

Tests that must be done because of the study that are **not** part of your regular care will be provided to you free of charge. The study will also assist with travel expenses and provide cafeteria vouchers if needed on the day(s) you are scheduled for tests related to the study. If long distance traveling is incurred, we will work with the Marfan Foundation to reimburse travel expenses.

May I withdraw from the study?

Your decision to join the study is completely voluntary. You may say no to joining, or you may withdraw from the study at any time. Deciding to not join the study or deciding to withdraw from the study will not affect your medical care now or in the future.

Confidentiality

You have a right to privacy, and your involvement in this research study will remain private. Your name will not be used in any published report about this study.

For More Information

Pediatric Heart Network Web site:
www.pediatricheartnetwork.com

National Marfan Foundation Web site:
www.marfan.org

Local Marfan Trial Site: Vanderbilt University
Site PI: Larry W. Markham, MD
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