

## PEDIATRIC HEART DISEASE CLINICAL RESEARCH NETWORK



Information for The Marfan Trial  
Patients and Their Families

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 my child join the study?

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

### What medication will my child take?

Your child will take either atenolol or losartan. You and your child will not know what medicine your child is 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 child's 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 your child.

### Taking part in this study involves:

*Measurement of growth:* Your child will have his/her weight, height, arm length, and leg length measured at each visit.

*Questionnaires:* At each visit, we will ask you some questions about your child to check for possible side effects of the study medication.

*Echocardiograms:* An echocardiogram is a painless test using sound waves that takes a picture of your child's heart. Your child may have as many as five echocardiograms for the study, one at each of the major study visits. For this test, your child will need to lie quietly on a table for about 30 minutes. Echocardiograms in infants and toddlers may require sedation (a medicine to allow your child to lie still) since older infants and toddlers are more active.

*Blood Tests:* If your child is less than 18 months old, s/he will have blood taken 3 times. Older children will have blood taken twice.

*24-hour Electrocardiogram (Holter monitor):* A Holter monitor is a painless test that records your child's heart rhythm for 24 hours. Your child will wear a small box about the size of a pager during normal activities for 24 hours. Your child will have a Holter before starting 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 child's regular care will be provided to you free of charge. The study will also pay for travel expenses and a meal on the day(s) your child is scheduled for tests related to the study. If you live far away from the study center and an overnight stay is required to complete study testing, you will be reimbursed for one night's lodging and meals.

### May I withdraw my child from the study?

It is up to you to decide if you will let your child join the study. You may say no to joining, or you may withdraw your child from the study at any time. Deciding to join the study or deciding to withdraw from the study will not affect your or your child's medical care now or in the future.

### Confidentiality

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

### For More Information

Pediatric Heart Network Web site:  
[www.pediatricheartnetwork.com](http://www.pediatricheartnetwork.com)

National Marfan Foundation Web site: [www.marfan.org](http://www.marfan.org)

<<Center contact information – affix label w/ PI and Coordinator names and #'s>>