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 = glossary definition

## Marfan Study Basics



The Marfan Trial studies Beta Blocker Therapy (Atenolol) versus Angiotensin II Receptor Blocker Therapy (Losartan) in Individuals with Marfan Syndrome. Marfan Syndrome (MFS) is a disorder that can affect the heart and large blood vessels as well as eyes, muscles, bones and lungs. The most serious problems can happen when the body's largest blood vessel, the *aorta* , becomes enlarged in individuals with MFS. This study is being done to compare two drugs (Atenolol and Losartan) to see if one is better than the other at slowing the speed of aortic enlargement. The study will also compare the kinds of *side effects*  that can occur when taking either of these medicines. The study will enroll 604 individuals, aged 6 months to 25 years of age. The study began in February 2007 and will take about 7 years to finish.

## Who can be in the study?



You or your child can be in the study if:


- There is a diagnosis of MFS according to *Ghent criteria* 
- 6 months to 25 years of age
- *Aortic root Z-score*  >3.0

## What do we have to do to be in the study?

If you or your child meets the requirements, the study will be explained to you in detail by one of the *study investigators* . Once your questions have been answered, you will be asked to sign an *informed consent form*  to enter the study. Some of the things that will happen during the study may be done only for study purposes. We will try very hard to time the tests required for the study with routine visits. We will also collect information on blood work and procedures that you or your child gets as part of routine clinical care.

This is what needs to be done in the study:

- We will review your medical chart from time to time to get data about your heart problem, the results of previous echocardiograms and how you have been treated.
- If you or your child is currently taking medication for MFS (like atenolol, propranolol, enalapril, lisinopril, ramapril, losartan, candesartan, or valsartan), the medication will need to be decreased over 2 weeks under medical supervision and then stopped for 2-3 weeks. After the medication is stopped, an *echocardiogram*  will be done.
- You or your child can then be *randomized*  to either Atenolol or Losartan and will take the study medication for 3 years. Neither you nor your doctor will be told which medicine you are taking but the study staff will know.

- A blood sample will be taken to see how your kidneys and liver are working before and after the study drug is started.
- You or your child will wear a *Holter monitor*  for 24 hours to check your heart rate each time that we adjust your study medication and at each of the study visits described below.
- Attend 5 study visits at the beginning of the study, 6, 12, 24 and 36 months after the first visit with an echocardiogram at each of the study visits. Some of these will be regularly scheduled by your doctor for your clinical care.
- We will contact you regularly to see how the medication is making you feel and if you notice anything unusual when taking the study drug.

Study personnel will be in contact with you frequently during the time your child is in the study. You are free to call the nurse or study coordinator at any time with any questions or concerns that you may have.

### **How long will we be in the study?**

You or your child will take the study drug for 3 years. We will continue to review your medical record for up to 5 years and we may contact you during that time to get more data on how you have been doing.

### **What are the possible benefits to being in this study?**

Although you or your child may not directly benefit from being in this study, your participation will allow your doctors to better understand which type of drug may be better for people with MFS.




### **What are the possible risks to being in this study?**

Possible risks of being in this study come mainly from the type of drug you or your child may take. Each drug is usually tolerated well but can have side effects. We will closely monitor for side effects throughout the study and will discuss with you what can be done to help or prevent them.

### **What are the costs to me to be in the study?**

There will be no additional costs for being in this study. Tests required by the study and that are not a part of regular care will be provided free of charge. You are responsible for all other costs related to your/your child's medical care such as hospitalization, surgery, drugs, lab tests and physicians fees which are considered standard medical care.

Who to Contact 

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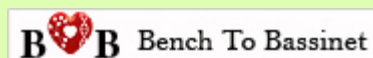
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