HELP FIND A BETTER WAY TO PREVENT ANOTHER CRYPTOGENIC STROKE

RESPECT
CLINICAL TRIAL
IDE#G990318
Cryptogenic stroke is a type of stroke that has an unknown origin. If you suffer a stroke, various tests are performed to determine the cause. These tests include CT scans, MRI, Ultrasounds and Echocardiograms. If the tests determine that you have a Patent Foramen Ovale (PFO) and there is no other explanation for the cause of your stroke — there is a high probability that you sustained a cryptogenic stroke.

**WHAT IS A PFO?**

Patent Foramen Ovale (PFO) is a term used to describe a small hole in the wall that divides the upper two chambers of the heart. A PFO may allow a blood clot to cross from one chamber to the other where it can enter the bloodstream and block an artery to the brain — resulting in a stroke.
There are several options to treat cryptogenic stroke and PFO, including:

* Lifelong medical management with anti-clotting blood thinners

* Surgical closure of the PFO requiring open-heart surgery

* Closure of the PFO with a non-surgical device

If you have a cryptogenic stroke, your physician will discuss these and other options with you. Some patients choose not to have any treatment at all.

**WHAT IS THE AMPLATZER® DEVICE?**

The AMPLATZER PFO Occluder is a non-surgical device for closure of the PFO. Delivered to the heart using a catheter, the AMPLATZER device is a nickel and titanium mesh disk filled with polyester fabric. The device is designed to close the PFO defect, which may prevent blood clots that cause stroke from entering the bloodstream.
WHAT IS THE RESPECT TRIAL?

The RESPECT Clinical Trial is a randomized clinical study required by the Food and Drug Administration (FDA) comparing the effectiveness of the AMPLATZER PFO closure device to treatment with blood thinners.

WHAT IS A “RANDOMIZED” CLINICAL TRIAL?

A randomized clinical trial is an investigational study comparing two treatments in which the treatment you receive is determined at random. In the RESPECT Clinical Trial, your chances of receiving the AMPLATZER PFO device or the blood thinner treatment are the same.

WHAT IF I DO NOT WANT THE TREATMENT I AM RANDOMIZED TO?

It is very important that you understand the randomization process before you agree to participate in the trial. You will not be forced to undergo any treatment you do not desire. However, if you refuse the randomized treatment, you will not be allowed to re-enroll in the trial to have another chance at receiving your treatment of choice.
HOW LONG WILL THIS STUDY LAST?

The RESPECT Clinical Trial is expected to last 2-5 years. You will be seen frequently until the study is completed. If you decide to participate in the investigational study, it will be important for you to come in for all required follow-up visits.

WILL I GET PAID FOR PARTICIPATING?

You will not be paid to participate in this clinical study. Your insurance company will be responsible for paying for all tests. If your insurance does not cover tests, there will be a reimbursement specialist available to assist you in getting coverage.

Thank you for considering enrollment in the RESPECT Clinical Trial. If you have questions, ask your doctor or call toll-free 1-800-899-3925. Or for a list of participating centers, visit the AGA Medical Corporation Web site at www.amplatzer.com/respect.