



Can you escape migraines?

Have you been diagnosed with migraine headaches? Have you tried taking preventative drugs for your migraines but they didn't seem to help?

You may be eligible for a new trial called **ESCAPE** sponsored by St. Jude Medical.

ESCAPE (*Effect of Septal Closure of Atrial PFO on Events of Migraine with Premere™*) is an approved clinical trial that studies the link between a heart condition called PFO and the incidence of migraines. Several clinical experiences have shown a strong association between the presence of PFO and migraines, and several physicians have shown that closure of PFO in patients with migraine and a previous stroke has been associated with a reduction in intensity and frequency of migraine attacks.

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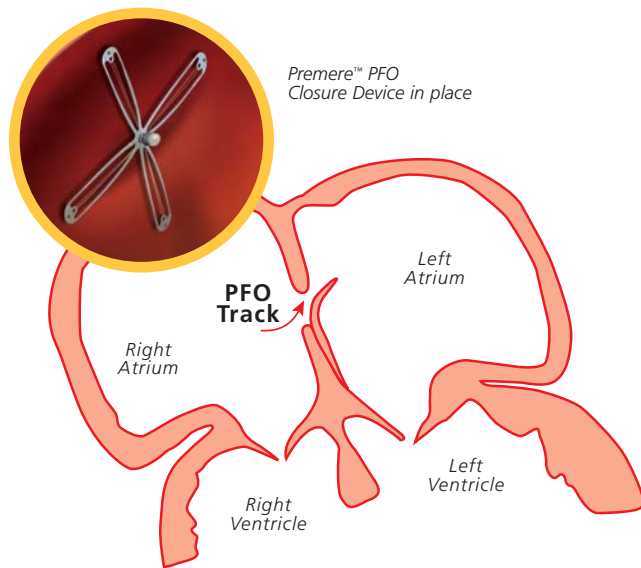
In the past decade, there has been growing evidence that patients with migraine headaches, particularly those with aura are more likely to have a patent foramen ovale (PFO) than a typical person.

While there is currently no proof that a PFO causes migraine headaches, several recent studies have shown a strong relationship between having a PFO and having migraine with aura.

Physicians want to know more about this relationship.

What is a Migraine?

A migraine is a headache that may have any of a number of common symptoms. The most common are a throbbing headache on one side of the head, sensitivity to light and noise, nausea, vomiting, and a lack of energy. Migraines usually last between 4 and 72 hours. Some migraine sufferers experience an aura, which are odd sensations in the eyes, ears, hands and may even result in a temporary loss of balance.



What is PFO?

PFO, or patent foramen ovale, is a heart defect that occurs when a small hole between the right and left upper chambers of the heart (atria) doesn't close in infancy. About 25 percent of all adults have a PFO, but the condition doesn't usually affect regular activity. Recent results have shown that up to 40% of migraine sufferers have PFO. The only way to know you have a PFO is for a doctor to perform a special test on your heart called a bubble study.

What is the link between a PFO and a migraine?

Several physicians have shown that closure of PFO in patients with migraine and a previous stroke has been associated with a reduction in migraine attacks. It is not clear why patients with a PFO would be more likely to have migraines, or why closing the PFO might decrease migraine attacks. It may be that blood that crosses the PFO, without being filtered by the lungs, has substances that trigger migraines. The only way to know if closing the PFO helps with migraine attacks is to do a clinical trial.

What is a clinical trial?

A clinical trial is a research study in volunteers to answer specific health questions.

Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people and ways to improve health. Clinical trials like the ESCAPE trial determine whether experimental treatments are safe and effective in treating health problems. Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical knowledge. You can learn more about clinical trials at www.clinicaltrials.gov

To find out more about the ESCAPE Migraine trial or to find out if you qualify, go to www.ESCAPEmigraine.com.

What is the ESCAPE clinical trial?

The ESCAPE migraine trial is a clinical trial that will evaluate the benefit of PFO closure in patients with migraine headaches who also have PFOs. Patients who have a PFO and migraines, who qualify for the trial and who choose to participate will be randomly assigned to have their PFO closed using a device called the Premere™ PFO Closure System. All patients who enroll in the trial will be asked to keep a detailed electronic diary of their migraines for one year.

Every patient in the trial will be sent to a cardiologist for an evaluation of their heart that will require a minor procedure and cut in the leg. For more information about this procedure go to www.ESCAPEmigraine.com.

The goal is to determine whether or not using a device to close the PFO will actually improve migraine headaches enough to be a therapy option for patients with migraine. During the ESCAPE clinical trial, patients will NOT take preventive migraine prescriptions. Patients will not know if they received the PFO closure device until they finish the one-year trial. This will help the trial determine the effectiveness of PFO closure alone.

How do I know if I qualify for the ESCAPE trial?

Ask your migraine physician if the ESCAPE trial may be right for you, or go to www.ESCAPEmigraine.com to get more information and to take a quick and simple survey.

What should people consider before participating in a trial?

People should know as much as possible about the clinical trial and feel comfortable asking the members of the health care team questions about it, the care expected while in a trial, and the cost of the trial. A research coordinator in this office can answer your questions about the trial. Participants would be subjected to the additional risk of an interventional procedure. The ESCAPE trial, like every trial in the US, has been carefully evaluated by an independent team of doctors, nurses, and consumer advocates to be sure that the trial is ethical and the rights of trial participants are protected.