The Ins and Outs of Clinical Trials for AFib

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Should I Participate in a Clinical Trial?

If you have a diagnosis of atrial fibrillation, or are at risk for developing the condition, you may want to participate in a clinical trial for Afib.

What Are Clinical Trials?

Clinical trials are tests that researchers conduct to evaluate the safety and effectiveness of treatments for AFib and other conditions.

Researchers use trials to evaluate the effects of medications, procedures, medical products, and other types of interventions. For example, a study may be conducted to determine if a special diet reduces episodes of AFib. A new procedure for performing cardioversion may be evaluated. New medications might need to be tested to see if they are safe, effective, and well tolerated. Medication doses are tested and drugs are compared to see which ones are most effective.

Clinical trials may be used to evaluate the effects of meditation or exercise on AFib. The use of clinical trials ensures the development of effective and safe treatments for AFib and other health concerns.

Phases of Clinical Trials

In the USA there are clinical trials and observational studies. In the USA and many other countries, clinical trials fall into one of five categories. You are most likely to participate in a phase two, three, or four clinical study.

The following is an example of the phases in a medication trial.

- **Phase 0:** A small study may be conducted on a very limited number of people to see what kinds of effects a diluted dose of a medication or substance has on the test subjects. The substance is not being evaluated for a specific use. It is just being looked at to see what actions it has. It is unlikely that you would participate in this kind of study.
- **Phase 1:** Clinical studies are conducted on healthy individuals who do not have AFib. The purpose of this kind of study is to evaluate the safety of the medication. Investigators note the effects of the drug, its side effects, and the frequency of side effects. This kind of research provides investigators with information about how the drug is used in the body and how it is eliminated.
- **Phase 2:** You may be a candidate to take part in a phase two clinical trial if you have AFib. Researchers often compare a medication with a placebo or another medication to see how well the studied drug works. In addition to evaluating safety, the purpose of a phase two clinical trial is to see if a treatment potentially offers benefits for people who have a certain condition.
- **Phase 3:** These are often large scale studies. The medication is administered to a wide array of individuals, in various doses. The researchers continue to evaluate the drug’s safety and effectiveness.

This is where the medication is “fine-tuned.” A phase three clinical trial is the final stage of testing that drug manufacturers are required to perform before the government makes a decision whether or not to approve the drug for use or not.

- **Phase 4:** Once a drug is approved for use by the public, ongoing phase four studies occur. Manufacturers are required to conduct phase four clinical trials, which are designed to ensure the public that the drug is effective and safe for use.

Where Are Clinical Trials Conducted?

Clinical trials are conducted worldwide. They are conducted in a wide array of settings. You may be able to participate in a clinical trial right in your hometown.

Some clinical research is conducted at universities and by pharmaceutical companies. Many studies take place in hospitals affiliated with universities.

Is Participating in a Clinical Trial Expensive?

No. If you are participating in a trial for a new medication, for example, you will be provided with the medication and related costs free of charge. If you need to travel to participate in a clinical trial, you may be compensated for your time and expenses.

Why Should I Consider Participating in a Clinical Trial?

You will help researchers learn about the most effective ways to prevent and treat atrial fibrillation. You may receive a cutting edge treatment which controls symptoms better than other treatments.

Next page: some things to keep in mind before signing up, and where to find atrial fibrillation clinical trials.

Considerations

It’s important to know that if you enroll in a clinical trial for a medication, you do not get to choose the medication you receive. In order for there to be no bias, most clinical trials are conducted using a double blind method. This means that neither you nor your doctor will know what medication you are receiving.

Should you experience a bad reaction to a medication you will receive the proper medical treatment. Depending upon how you feel and the severity of the reaction, you may need to withdraw from the study. You may withdraw from a clinical trial at any time.

Participants of each project must meet certain criteria. For example, you may need to have developed AFib within a certain time period, or you may or may not be included due to age or other medical conditions.

The length of time that a study lasts varies greatly. It may be one day or it could go for many years.

Is a Clinical Trial Right For You?

The decision to participate in a clinical trial is a personal one. Consider the pros and cons of a particular study prior to enrollment. If you do participate, you are providing humanity with a great service, and you may be one of the first people to take advantage of a cutting edge treatment.

However, participation in a clinical trial is not best for everyone. Only you can make the decision whether to explore participating in a clinical trial or not.

After Admission

If you decide to get involved in a study for AFib sufferers, you may not be sure what the next step may be. Carefully review the informed consent form and the package received from the research team. Be sure to ask any questions you may have.

Your status at the clinic will be either as an inpatient (meaning you are formally admitted to the hospital with a doctor's order) or an outpatient (where you get various medical services including observation, lab tests, or other investigations; but, you will not be admitted to the hospital as inpatient).

Here are some suggestions for what to bring with you:

- Medication, including any vitamins and supplements
- Casual clothes, including pajamas and a robe if you wish
- Comfortable shoes or slippers
- Toiletries, including small razors and hair dryers if the clinic allows it

For your safety and security, the research clinic may limit the use of certain electrical devices, such as cell phones, in certain areas of the hospital. Most clinics will allow tablets and laptops.

You can either leave money or jewelry at home or they can be placed in a locked safe while you are in the clinic.

Are There Any Clinical Studies Recruiting Volunteers Now?

Several trials are listed on the USA's clinical trials website that currently need volunteers with AFib.

These trials are investigating the effectiveness of a new technique used for performing ablation therapy, evaluating a blood clot prevention medication, testing a device designed to reduce irritability of the tissues within the heart and looking at the impact of things like implantable devices, lifestyle, and surgical procedures for the treatment of AFib.

How Do I Learn About Clinical Trials?

Ask your cardiologist if she or he knows of any clinical trials being conducted that need volunteers. You can also check with colleges and universities. Sometimes, advertisements for subjects are placed on television or in newspapers.

Most government clinical trial websites provide information about ongoing trials, contact information for participating in trials, and follow up reports about previously conducted studies. Depending upon the country, all clinical trials may not be listed on the government website.

Here is the contact information of government resources for some countries:

- **USA** – National Institutes for Health
- **UK –** United Kingdom Clinical Trials Gateway
- **Canada –** Health Canada's Clinical Trials Database
- **Australia –** Australian Clinical Trials

For information about clinical trials being conducted in other countries do a web search using the name of the country and the term "clinical trials."