

More Frequently Asked Questions

What are the advantages of participating in ISCHEMIA?

You may benefit from being in this study by receiving lifestyle counseling. You will regularly see and hear from the study doctors and coordinators. They will carefully review your care. You may get stents and some medications at no cost to you. Your participation will help us understand the best way to treat patients with ischemia.

Will it cost me anything if I participate?

Your medical care before, during, and after the clinical study is usually billed to your health insurance. The heart X-ray (CCTA) will be paid for by the study sponsor since it is being done only for research purposes.

Are there any new drugs, devices, or procedures being tested?

No. The study compares two common treatments that doctors around the world use for patients with ischemia.

What happens to my medical care after the study?

After the study ends, you will still receive medical care from your own doctors, but you will not have any more scheduled study visits.

Will my personal information be kept confidential?

Yes. You have a right to your privacy, and your participation in this study will be kept private.

Who is organizing and funding the study?

The study was designed by expert doctors and scientists from many leading hospitals and universities. The National Institutes of Health in the United States is funding this study.



Where can I get more information about this study?

More information about this clinical trial is on the following public websites:

www.ischemiatrial.org

www.clinicaltrials.gov

Whom to Contact

Principal Investigator:

Study Coordinator:

Address:

Phone:

Email:

Fax:

What is



is·che·mi·a

Pronunciation:
[ih-skee-mee-uh]

noun

A decrease in the blood supply to an organ, caused by a complete or partial blockage of an artery.



What is ischemia?

When a heart artery narrows, part of the heart may not receive enough blood to work normally. Doctors call this ischemia. The main symptom of ischemia is chest pain (angina), but not everyone with ischemia has symptoms. Ischemia is associated with a higher risk of having a heart attack.

How is it treated?

Doctors use two standard ways to treat ischemia of the heart.

- One way uses **medicines** and recommends **lifestyle changes** to control chest pain and lower the risk of complications, such as a heart attack.
- Another way adds the use of a procedure called **cardiac catheterization** to see your heart arteries. If the arteries are narrowed, either **stents** are put in the narrowed arteries or **surgery** is done to bypass them to increase blood flow to the heart muscle. Medicines are also used and lifestyle changes are recommended.

Which treatment is the better and safer choice?

Both treatments are commonly used by doctors worldwide. However, doctors do not know which of these treatments is better and safer to use when a patient's stress test shows ischemia.

The ISCHEMIA clinical trial will compare these two standard treatments to find the better and safer treatment to use when a patient's stress test shows ischemia.

What is a clinical trial?

A clinical trial is a research study with volunteers that is designed to improve care for patients with health problems. Trials usually compare different treatments like medications, procedures, devices or health management plans.

Why participate in a clinical trial?

Participants in clinical trials can play a more active role in their own healthcare, receive new treatments before they are widely available, and help others by contributing to medical research.

ISCHEMIA
International Study of Comparative
Health Effectiveness with Medical
and Invasive Approaches

What is the ISCHEMIA study?

The ISCHEMIA study is a clinical trial that compares two standard treatments for patients with ischemia of the heart to learn which one is better and safer:

- Starting treatment with cardiac procedures such as cardiac catheterization, and then stent placement or bypass along *with* medicines and lifestyle changes, or
- Starting treatment with medicines and lifestyle changes alone, with a plan to use cardiac procedures only if they are needed

Approximately 8,000 people at approximately 400 different hospitals and medical facilities around the world will participate in this study.

Can I participate in ISCHEMIA?

You may be able to volunteer to join this study if:

- You are 21 years old or older
- Your recent heart stress test shows that you have ischemia.

Talk to your doctor or contact the ISCHEMIA study staff to learn more.

What happens if I join this study?

If you want to take part in this study, after you agree to join we will ask you some questions about your health, review your medical records, and send your recent stress test to a laboratory to confirm the results.

You may have some additional tests or procedures. These tests are commonly used in standard care for heart ischemia. They may be done even if you do not join the study.

You may have a special type of X-ray of your heart called a Coronary CT Angiogram [CCTA]. This is not a new or experimental procedure.

If the tests show that you are eligible to join the study you will be randomly assigned to one of the two standard treatments, and your treatment will start.

Your doctors will discuss these treatments in detail with you before any procedures are done.

There are an estimated 9 to 18 study visits over 1½ to 6 years, depending on when you enter the study. Study visits are in-person and some by telephone or email. The in-person visits last about 1 hour. The phone calls last 15 to 30 minutes.