www.preemptstudy.org

PRE-EMPT Study Frequently Asked Questions

How is Heart Disease Detected?

Plaque in your heart's arteries can accumulate calcium as it grows. This calcium isn't a blockage—it's more like a shadow showing where plaque is. We can easily spot it on a CT scan because calcium shows up clearly on X-rays.

CT scans take hundreds of flat pictures and combine them into detailed 3D images of your body. When we add contrast dye, it becomes a CT angiogram, which lights up your blood vessels. The scan creates a 3D model of your arteries that your doctor can rotate and examine from every angle. CT angiography is less invasive than traditional angiography, which uses a catheter inside your blood vessels.

What is the PRE-EMPT study?

The PRE-EMPT Trial, funded by the National Institutes of Health (NIH), is testing whether we can detect and treat early signs of heart disease, before symptoms appear and before heart attacks happen.

This study is asking two questions: (1) How can we find people who have plaque? (2) If plaque is present, how best to treat it?

Screening Process:

1. Coronary Artery Calcification (CAC) Scan – A quick, low-radiation CT scan to detect calcium in heart arteries, or previous CT scan showing calcified plaque.
2. Home Blood Sample – A painless, at-home blood collection kit.
3. Coronary Computed Tomographic Angiogram (CCTA) Scan- A detailed CT scan using contrast dye to visualize the heart arteries and detect plaque that has not calcified yet.

Treatment Process:

If early plaque is found, and you qualify for the treatment trial, you'll be randomly assigned to one of four groups. You'll take two pills daily for two years and undergo a final CCTA scan to measure changes in your heart arteries.

Study drug groups:

1. Statin + Colchicine
2. Statin + colchicine placebo
3. Colchicine + statin placebo
4. Two placebos

Why does early heart screening matter?

By age 40, almost half people in the U.S. have heart disease without symptoms. This early heart disease consists of plaque or cholesterol deposits in the walls of the heart arteries that can break apart and cause a heart attack. Early undetected heart disease can be deadly: it causes 1 in 5 deaths among people younger than 65 years.

Read more: Sagris, M., Antonopoulos, A. S., Theofilis, P., Oikonomou, E., Siasos, G., Tsalamandris, S., Antoniades, C., Brilakis, E. S., Kaski, J. C., & Tousoulis, D. (2022). Risk factors profile of young and older patients with myocardial infarction *Cardiovascular Research*, *118*(10), 2281–2292. https://doi.org/10.1093/cvr/cvab264

Who is the study for?

You may qualify for the study if you are a man, age 30-50, or woman, age 40-60, without clinical heart disease, but you have any of the following:

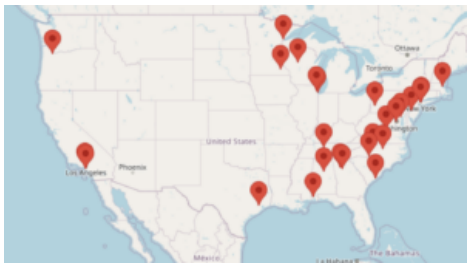
- Several heart disease risk factors (like high cholesterol, hypertension, smoking, or obesity)

- A family history of early heart disease: first-degree relative (parent, sibling) who had a heart attack, stroke, or arterial revascularization before age 55 (men) or 65 (women)
- A CT scan within the last three years showing coronary artery calcification, or a coronary artery calcium (CAC) score between 1–99

PRE-EMPT is not for:

- People with heart attack or stent or symptoms of heart disease, such as chest pain, palpitations or shortness of breath
- People with diabetes
- People with extremely high cholesterol (familial hyperlipidemia)
- People who are pregnant or trying to get pregnant

You must be willing to go to one of the approximately 20 U.S. study sites to complete imaging tests at the start and at 2 years.



How do I take the next steps?

From every page of this website, you can interact with a private and protected tool powered by AI and custom-designed to inform you about the study and to see if you may qualify. PRE-EMPT Connect will quickly help you find out if you qualify for enrollment in the study through a simple question-and-answer format. It will also allow you to ask your own questions about the study before you take the next step with a live study coordinator. It will keep your health information safe. Click the button below, "See if you qualify."

If you do not want to use the AI chatbot, you can contact a study coordinator by finding a location near you on the website and contacting them directly.

What's next if I qualify for the PRE-EMPT study?

We will start the screening process to look for calcium in your heart arteries. Plaque in your heart's arteries accumulates calcium as it heals. This calcium isn't a blockage—it's more like a shadow showing where plaque has been for a while. We can easily spot it on a CT scan because calcium shows up clearly on X-rays. The riskier plaque has not yet calcified, called non-calcified plaque, and we can only see it with a coronary CT angiogram, not by the CAC scan. That is why we need both studies to know if you qualify.

CT scans take hundreds of flat pictures and combine them into detailed 3D images of your body. When we add contrast dye, it becomes a CT angiogram, which lights up your blood vessels. It's like giving your doctor a 3D model of your arteries they can rotate and examine from every angle.

It's easier on your body, too. CT angiography is less invasive than traditional angiography, which uses a catheter inside your blood vessels. Read more about the cardiac CT calcium score.

About Step 1: Informed consent

Your informed consent is an important part of joining the PRE-EMPT study. Before you decide whether to take part, a member of the study team will explain what the study is about, what participation involves, and any possible risks and benefits, in clear and easy-to-understand language. You'll have time to review the consent form, ask questions, and discuss the study with others if you wish. Consent can be completed in person or remotely using a secure electronic process. You must sign the consent form before any study-specific procedures take place, and you will receive a copy for your records. Taking part is completely voluntary, and you may choose not to participate or to stop at any time

About Step 2: Coronary Artery Calcium (CAC) scan

When plaque heals in your heart's arteries, it can accumulate calcium. This calcium isn't the same as a blockage—it's more like a shadow marking where plaque is. We can see calcium clearly on a CT scan because it shows up well on X-rays. That makes it a quick and easy way to spot early signs of heart disease—even before symptoms appear. The CAC scan is a quick, low-radiation CT scan that checks for calcium in your heart arteries.

What to expect:

- You'll lie on a table that slides into a CT scanner.
- Sticky pads will be placed on your chest to monitor your heart rhythm.
- You may be asked to hold your breath briefly.

- You won’t have to undress or have an IV placed.
- The scan takes less than 15 minutes, but the visit may last 30–45 minutes.

If you've had a qualifying CAC scan or chest CT in the past 3 years, you may not need this step. Let your study site know if you have had a prior test like this.

About Step 3: A simple, painless way to give a blood sample from home

Before your CCTA, you'll receive a home blood collection kit in the mail. It uses a small device to painlessly collect blood from your upper arm. You'll mail the sample back in a prepaid box. No needles. No clinic visits. No stress.

How It Works:

- Stick it on your arm – The device uses a soft adhesive to stay in place.
- Press the button – A tiny lancet gently opens the skin and creates a light vacuum to draw blood.
- Wait 5 minutes – Blood from small vessels under your skin flows into a small tube. While not 100% pain free, you may not even feel it!
- The lancet automatically retracts after use, and the device is single-use and sterile.
- Peel it off and pack it up – Just remove the device, seal the sample, and drop it in the prepaid mailer and send.

While minor bruising or a small mark may occur at the collection site, these are typically temporary and fade quickly.

That's it. You're done. Want a video tutorial? Watch this short video.

About Step 4: Coronary CT Angiogram (CCTA)

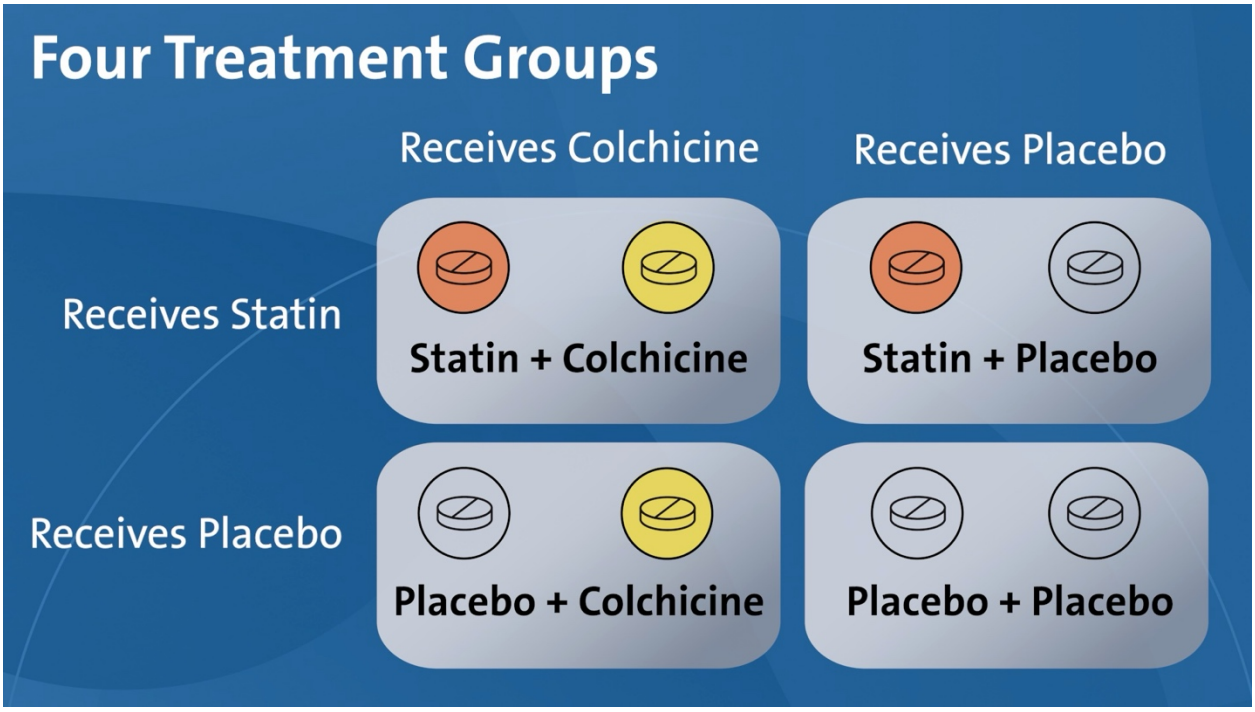
If your CAC scan shows calcium spots and your blood test indicates no unexpected abnormalities, you'll have a CCTA next. This is a more detailed CT scan that uses contrast dye to look inside your heart arteries and measure early plaque. It shows both calcified and non-calcified plaque, including the soft, inflamed plaque that can rupture and cause heart attacks. It's especially useful for spotting soft non-calcified plaque not seen by a CAC scan. What **to expect:**

- You'll receive contrast dye through an IV.
- You may be given medications like beta blockers or nitroglycerin to improve image quality.
- The scan takes about 15 minutes, and the full visit may last around an hour.

The PRE-EMPT treatment trial

What is the treatment trial about?

If your scans show early plaque, you may qualify for a 2-year treatment trial. You would be randomly assigned to one of four groups: statin + colchicine, statin + placebo, colchicine + placebo, or two placebos. Everyone gets lifestyle coaching as well.



- You'll take two pills once a day, and neither you nor your study team will know which group you're in. Two study drug bottles will be mailed to your home every 3 months. They will contain either the active drug (statin or colchicine) or the matching placebo. You will also get a weekly pill box to keep track of taking them.
- You'll receive a Fitbit, also in the mail, and be connected to personalized, cardiologist approved advice designed to improve your heart health.
- You'll complete brief surveys by text messaging about your health and quality of life at the beginning, at 2 weeks, and at 1, 2, 4, 6, 9, 12, 15, 18, 21 and 24 months.
- You'll have phone check-ins at 3, 12, and 24 months.
- 20% of participants will be asked to complete another at home blood collection at 3 months.

At the end of the study, you'll have another at home blood collection and return to the site to have a second CCTA scan to see if your plaque has changed.

How Rosuvastatin works

Statins (like rosuvastatin) are cholesterol-lowering medications which lower LDL cholesterol, which is the "bad" cholesterol that contributes to plaque. Statins reduce the amount of plaque and stabilize it by reducing inflammation. In trials, statins reduce heart events by 25 – 35% in people with no prior heart disease, called primary prevention patients.

Download study drug brochure.

How Colchicine works

Colchicine is an anti-inflammatory medication sometimes used for gout. A lower dose is used in heart disease, where it calms inflammation inside artery walls, prevents plaque rupture by stabilizing the plaque structure, and reduces non-calcified plaque (NCP), which is the soft, high-risk kind. Colchicine works by blocking inflammatory signals (like IL-1β and IL-18) and reducing immune cell activity. In trials, it reduced heart events by 31% in people with stable coronary disease.

Download study drug brochure.

Why is PRE-EMPT testing two different drugs?

Even with statins, some risk remains, especially due to inflammation. PRE-EMPT is testing whether combining statins and colchicine can target both cholesterol and inflammation to get an additive effect.

What is a placebo?

A placebo is a pill that looks exactly like the study drug, but it doesn't contain the study drug ingredient. It's used in research to remove bias to more clearly confirm how a treatment works. By comparing people who take the study drug to those who take the placebo, researchers can see if the benefits are from the drug itself and not just from other factors like lifestyle or expectations.

Placebos are safe and carefully made to match the real medication in size, shape, and color, so no one knows which one they're taking. This is very important part of high-quality reliable research to keep the results fair and unbiased.

Your Fitbit + Compensation

If you enroll in the PRE-EMPT treatment trial, you will receive regular, personalized heart health information and tips for healthy living, such as the information included in these easy steps you can take to live a healthier lifestyle and these for active and mindful living.

Do I get to keep my Fitbit?

As part of PRE-EMPT, you'll receive a Fitbit, an easy-to-use device that tracks your physical activity, sleep, and heart rate, mailed to your home. It syncs with your smartphone to help guide healthy lifestyle changes.

Whether you have a question, want to share an update, or just check in, help is just a tap away. We will ask you to wear your Fitbit consistently during the study for reliable step counts and sleep data, and you will see this information regularly in the app. Also, the Fitbit is yours to keep at the end of PRE-EMPT.

Will I be compensated for my time?

You will be compensated for your time in completing the study steps. Although the study does not directly reimburse participants for transportation, childcare, or other miscellaneous costs associated with participating, the compensation should help cover most of your costs. We share these amounts with you in the informed consent form.

What else is involved?

What are the risks?

Here's what to expect in PRE-EMPT, and how we keep your safety in mind.

Radiation exposure from the imaging scans is low, similar to what you'd get from a few months of natural background radiation. You may feel brief discomfort or flushing during the CCTA scan, but it's brief.

Contrast Dye (used in CT angiography) helps highlight your blood vessels, resulting in clearer images. Rare risks include allergic reactions or effects on kidney function—especially if you have existing kidney issues. We screen for this in advance.

The study drugs in PRE-EMPT are commonly used, and FDA-approved. This means they are familiar to doctors. What you might expect with Rosuvastatin (a cholesterol-lowering medication) are mild muscle aches. What you might expect from Colchicine (an anti-inflammatory medication) is mild, time-limited stomach upset. There are some rare risks or more serious reactions, but these are

uncommon and usually reversible if the medication is stopped. These risks are generally low and monitored throughout the study. You should always inform the study if you think you are having a side effect due to the medication.

I don't live near one of the PRE-EMPT sites. Can I still take part?

PRE-EMPT uses coronary CT angiography (CCTA) to get high-quality images of your heart. These scans are done on study-verified scanners to ensure the results are accurate and reliable—so we can confidently learn how to prevent heart disease.

To take part in PRE-EMPT, you'll need to travel to one of our 20+ study sites 1 or 2 times during the study for the screening tests (CAC and CCTA, or just CCTA) and then the 24-month CCTA. The study does not reimburse travel costs, so it's important to make sure you can get to a site when needed. If you plan to move during the study, this may affect your ability to continue. If a move is likely, this study may not be the right fit for you.

How long does the study last?

The screening portion of the study may take up to 4 months. The treatment portion of the study will last for about two years. We will also call or text you a year after your time in the study is over to follow up on how you have been since the study ended.

Why PRE-EMPT matters and why you matter

We don't know if you will personally benefit from participating, but you will get heart disease screening and will be informed if we find anything unexpected or abnormal.

You may want to participate to help doctors learn how to care for younger adults who appear healthy but are at risk for an early heart attack or stroke. Imagine identifying and treating the root cause at age 35 or 45 and preventing a heart attack at 65. If successful, PRE-EMPT could redefine prevention and bend the curve on heart disease deaths.

What is clinical research?

Clinical research is a way for doctors to learn about health by working directly with patients. These studies help us understand how to prevent, diagnose, and treat medical conditions—and how to improve health for everyone.

Clinical research helps:

- Discover new medicines, treatments, and tools to diagnose and prevent diseases.
- Test how well current treatments work and how safe they are.
- Understand what increases the risk of getting sick.
- Find better ways to keep people healthy and improve their quality of life.

There are two main kinds of clinical research:

- Observational Studies: Researchers watch and collect information without changing anything. For example, they might follow a group of people over time to see how a disease develops.
- Clinical Trials: Researchers give participants a treatment or medicine to see how it works. These studies often compare the one treatment to another one or a placebo (a look-alike with no active ingredient).

PRE-EMPT is a clinical trial comparing two commonly used medications for heart disease to each other and to a placebo.

What happens in a clinical trial?

- Participants are randomly placed into different groups to test how treatments compare. Often, neither the person nor the researcher knows who is getting which drug, to reduce bias.
- Researchers closely monitor safety and results.
- Everyone who joins must give informed consent, meaning they understand the study and agree to take part.

What are the benefits of clinical research?

Clinical research is essential for medical progress. It helps create better treatments, improves how care is delivered, and deepens our understanding of health and disease.

- It leads to new discoveries that can improve health and save lives.
- It gives doctors and patients better information to make decisions.
- It allows people to contribute to science and help others by participating.

Does clinical research follow rules to protect participants?

- People must be fully informed and agree to take part.
- Their personal information is kept private.
- Researchers work to make sure participants are safe and treated with respect.