



What is the PREVENTABLE study?

PREVENTABLE is one of the largest studies in older adults. The purpose is to learn if taking a statin could help older adults live well for longer by preventing dementia, disability, or heart disease.

What is a statin?

A statin is a commonly used drug to lower cholesterol. Statins are commonly prescribed to patients with a history of a heart attack and stroke. Atorvastatin, also called Lipitor, is the study drug in PREVENTABLE. It is a type of statin that is well known and has been prescribed to older adults for many years.

I've heard that there are some side effects to taking statins such as muscle aches. Should I be worried?

Occasionally, people experience muscle aches, which is also called myopathy or myalgia. About 5 out of every 100 people (or 5%) report having muscle aches. Muscle complaints are quite common even among people not taking statins.

If you develop muscle pain after starting the study drug (which could be atorvastatin or placebo), you should talk to your study doctor. It can sometimes be difficult to determine if the muscle pain is caused by the study drug or due to other causes, like arthritis. You can discuss options for stopping your study drug for a period of time and then resuming at a lower dose or permanently stopping your study drug with your study doctor.

What are good resources to learn more about statins?

There is a lot of misinformation about statins from stories in the news or conversations with family and friends. It can be difficult to find good resources, with trustworthy medical information to guide your decisions about statins and your health. Here are some reliable resources about statins if you are interested in learning more:

In English

JAMA Cardiology Patient Page: Statins and the Prevention of Cardiovascular Disease

<https://jamanetwork.com/journals/jamacardiology/fullarticle/2599102?resultClick=1>

Statin side effects: Weigh the benefits and risks: Mayo Clinic

<https://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statin-side-effects/ART-20046013?p=1>

In Spanish

Estatinas, JAMA Cardiology Patient Page

<https://sites.jamanetwork.com/spanish-patient-pages/2013/hoja-para-el-paciente-de-jama-130403.pdf>

Efectos secundarios de las estatinas: considera los beneficios y los riesgos, Mayo Clinic

<https://www.mayoclinic.org/es-es/diseases-conditions/high-blood-cholesterol/in-depth/statin-side-effects/art-20046013?p=1>



Why would I join a 5-year study when I don't have to?

By joining this study, you will help us understand the potential benefit of statins in people over 75 years. You will also receive regular monitoring by medical professionals, including yearly memory screening. The study lasts many years as it is important for Researchers to follow changes over time.

This is a unique opportunity to join a larger effort and feel a part of something bigger to advance medical knowledge for adults over 75 years. You would be joining up to 20,000 other older adults who are also interested in helping answer this question.

My lipid level is normal, why would I want to lower it?

Atorvastatin, and all statin medications, do more than just lower cholesterol, or lipid levels. These drugs can also be anti-inflammatory and may help prevent memory loss, improve physical function, and even prevent cancer.

However, we don't really know. The PREVENTABLE trial study will answer this question using randomization (a coin flip to decide if you take atorvastatin or placebo). We need more evidence from studies like PREVENTABLE to better understand the role and benefits of statins in older adults.

If my lipid level is already slightly elevated, why would I take a placebo instead of getting a statin from my physician?

The majority of individuals age 75 or older without heart disease are not taking statins. This is largely due to uncertainty about their effectiveness. However, starting a statin even after age 75 may help lower the risk of developing dementia. Talk with your doctor to discuss if you would be a good fit for PREVENTABLE, or if you should be on a statin at this time.

What if I have an urgent health issue and I don't have a lipid level in my health record or my doctor wants to know it?

There is no health emergency that would require a recent lipid level. Lipid levels are most useful to help understand an individual's long-term health risk to prevent heart disease. In PREVENTABLE we do not want lipid levels checked, as it would reveal if a participant were taking a statin. If a lipid level is needed for a study participant's care the doctor can order one.

I am more sensitive to medications in general, would this study be right for me?

Statin medications are very safe. If you experience any issues with the study drug you can notify your study doctor. We want to ensure participants are comfortable taking the study drug. If you are unsure about taking the study drug, it is best that you not participate.

I already made the educated decision to not take a statin. I prefer a natural approach and don't like to take medications in general.



It is important to understand the why PREVENTABLE is being done before deciding to participate. You can talk with your study team and ask any questions you may have. We are aiming to enroll a diverse population to help understand if taking a statin could help older adults live well for longer by preventing dementia, disability, or heart disease.

I'm going to take a statin for 5 years and not know my lipid level the whole time?

There is no safety concern to not check a lipid levels for participants in PREVENTABLE. In addition, there is no recommendation for routine lipid monitoring in people over 75 without heart disease from either the United States Preventive Services Task Force, the American College of Cardiology, or the American Heart Association.

Checking lipid levels in people who are taking are used to evaluate dose and confirm. Repeated measurements are less important in healthy older adults as lipid levels are very unlikely to change after age 65. This is supported by data from National Health and Nutrition Examination Surveys in which lipid levels were found to be relatively stable between those age 60-69 and those over 70.

The purpose of not drawing routine lipid levels in PREVENTABLE is to keep participants and researchers from knowing if they are on study drug or placebo. This process helps prevent bias in the research results.

I am in my mid-nineties, and have never participated in research before. Am I too old for this study?

This is a study about function and not age. We encourage folks in their 90s to consider participating if they have eligible physical and cognitive function. If statins extend the cognitive or physical function of someone in their 90s that may improve quality life years for 25% of their remaining lifetime. What a gift! While some in their nineties may think about narrowing their world, others may view contributing to science as an enduring part of their legacy. As they say, the older you are, the brighter you can shine.

What if I already have some memory loss? Can I still participate?

Yes! It is normal to have some memory changes as we age, particularly in our late 70s and 80s. This is normal aging and would not disqualify you from participating in PREVENTABLE. Even if you have "Mild Cognitive Impairment," which is a medical term for increased memory loss associated with aging, you would still be able to participate. In fact, it is important for us to learn from patients like you, to understand if statins may lower the risk of progressing to a diagnosis of dementia. However, if you have a diagnosis of dementia from your doctor, or if you take certain medications to enhance memory (for example, galantamine, rivastigmine, donepezil, or memantine), you are not eligible.

Is enrollment in PREVENTABLE open to patients outside of the site's health system (for example, a referral from an unaffiliated community physician?)

Currently, patients in the participating health systems are prioritized for enrollment in PREVENTABLE. A key component of PREVENTABLE is accessing data from participating health systems' electronic health system. Researchers will not be able to access this health data from participants who receive



care at nonparticipating health systems. If a primary care provider is outside of the system, but other routine health care such as labs, cardiology, or geriatric visits are inside the health system that might work. If a participant wants to establish care in a participating health system that would work.

If I am planning to spend extended time outside of the US for part of the year, can I still participate?

Yes, if you are planning to spend up to 3 months outside of the US, you can still participate and can request an early refill of study drug mailed to your US address in advance of your travel date. This is because the pharmacy is not able to ship outside the US.

If I plan to change my permanent residence by moving out of the country in the next 5 years, can I still participate?

Yes, as long as your date of move is not yet planned, as in possible but not definite, and/or if your planned move is at least two years after you first enroll. We will not be able to continue shipping study drug outside of the US once you move; however, you can request a refill prior to your move date to continue at least 3 months longer. After 3 months, you would permanently discontinue study drug use but stay in the study if you were willing to receive annual phone calls.

If I join PREVENTABLE, can I participate in a COVID-19 vaccine study?

Yes, of course. We are a pragmatic study with very few reasons you cannot join apart from the basic qualifications based on your medical history. Besides, everyone will be getting a vaccine for COVID before long anyway (hopefully).