



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

By joining this clinical trial, you will help us understand the potential benefit of statins in those over 75 years. You will also receive regular monitoring by medical professionals, including yearly cognitive screening. The trial lasts many years as it is important for us to follow changes over time to help guide treatment for others in the future.

Also, this is a unique opportunity to join a larger effort and feel a part of something bigger to advance medical knowledge. 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 lipid levels. These drugs also have anti-inflammatory actions and may help protect cognition, physical function, and even prevent cancer. However, we don't really know. Statin use for primary prevention may be associated with healthy habits, or statins may actively prevent dementia and cardiovascular disease. The PREVENTABLE trial will answer this question using randomization (a coin flip to decide if you take atorvastatin or placebo).

### **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 cardiovascular disease are not taking statins. This is largely due to uncertainty about their effectiveness. Talk with your doctor to see if you would be a good candidate for this study, or would need to be on a statin at this time.

### **What if I am in an emergency and I don't have a lipid level in my chart or my doctor wants to know it?**

There is no emergency which would require a recent lipid level. Lipid levels are most useful to help us understand an individual's long term cardiovascular risk to guide preventive treatment decisions. We do advise against checking lipid levels routinely while continuing on study drug as it would reveal if you were taking atorvastatin 40mg. If a lipid level were urgently needed for your care, your doctor would simply check one.

### **I am more sensitive to medications in general, so I don't think this study would be right for me.**

Statin medications are very safe [1-3]. Participation in the study is also voluntary. We also want to ensure participants have a high likelihood of staying on study drug after randomization has occurred. Therefore, if you have uncertainty about tolerating the study drug, it is best that you not participate.

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

It is important to believe in the study question prior to participation. In this case, we are following cardiovascular outcomes, but the main study question is around prolonging healthy life years free from new cognitive impairment, dementia and disability. We benefit from having health-minded older adults like you join studies. However, if taking a study drug is not something you are willing to do, it is best that you not participate.



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

There is no recommendation for routine lipid monitoring in those over 75 without cardiovascular disease from either the United States Preventive Services Task Force (USPSTF) [4, 5] or the ACC/AHA [6]. Lipid measurements after initiation of open-label statin are used to evaluate dose and medication adherence [6].

You would be on study drug with a 50% chance that it is atorvastatin 40mg. The purpose of not drawing routine lipid levels is to keep the study blinded and ensure the integrity of the study for determining the outcomes. There is no safety concern to not checking a lipid level in this setting.

Repeated measurements are less important in healthy older adults as lipid levels are very unlikely to change after age 65 [4]. This is supported by data from National Health and Nutrition Examination Surveys (NHANES), in which lipid levels were found to be relatively stable between those age 60-69 and those over 70 [7].

### **Is enrollment open to patients outside of the site's health system (e.g. a referral from an unaffiliated community physician?)**

A: We would prioritize patient enrollment to those within your health system. One of the cornerstones of the pragmatic design is pulling data from the Health Systems' EHR and participants outside the system will not be able to provide those data. The issues are (1) ability to track labs (2) implementing the EMR tools (3) availability of information needed for the site PI to be the prescriber of record and (4) the hospital system in which the participant is likely to be hospitalized in the event that is needed over time. If a primary care provider is outside of the system, but other routine health care where labs are obtained such as cardiology or geriatrics is inside the health system that might work. If a participant wants to establish care in a participating site, that definitely works since they can report historical data on the baseline form and all ongoing care would be therefore connected.

#### REFS

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4. *Lipid Disorders in Adults (Cholesterol, Dyslipidemia): Screening*. 2013; Available from: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lipid-disorders-in-adults-cholesterol-dyslipidemia-screening-2008#fullrecommendationstart>.
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