

Study Description

Regulation of Cholesterol Absorption: LDL Cholesterol Response To a Combination of Phytosterols and Ezetimibe Phyto 3

Who is doing the study?

Utah State University's Center for Advanced Nutrition has been selected to carry out a controlled feeding study of about 25 participants from the Cache County area. This is the third of four feeding trials funded by the National Institute of Health. Dr. Michael Lefevre is the Principal Investigator, and Dr. Jim Davis is the Medical Director.

Description of study.

Phytosterols, also known as plant sterols, occur naturally in some foods, mostly in vegetable oils, nuts and legumes. Phytosterols have been shown to lower LDL cholesterol by blocking the absorption of cholesterol in the intestine. An FDA-approved drug, ezetimibe, also lowers LDL cholesterol by blocking intestinal cholesterol absorption. It is believed that ezetimibe and phytosterols block cholesterol absorption in different ways, and thus, their effects could potentially enhance one another. Combining phytosterols with ezetimibe has been tested before in humans with no serious outcomes; however, it is still considered to be investigational. The information obtained from your participation in this study may be used to support and possibly extend the current dietary recommendations for phytosterol use.

How to qualify.

In order to qualify for this study, you must be relatively healthy and not taking any cholesterol-lowering drugs. You must successfully complete a series of three clinic visits which will take place at the USU Student Health Center. During these visits, your health and eligibility status will be assessed through interviews, questionnaires, and laboratory tests involving blood and urine samples. On the third clinic visit, our study physician will make the final determination of your eligibility by completing a physical exam. Participants will be provided with all meals for 9 weeks, and may earn up to \$500 upon completion.

What we expect from you.

- *Eat ONLY the food provided to you during our feeding trial comprised of THREE Study Periods, each lasting 21 days. There will be short breaks between each 21-day feeding trial where you can return to your normal eating patterns.*
- *Eat breakfast and dinner at our facility on campus (The Junction) Monday-Friday. Lunches and week-end meals will be provided to you in take-out fashion.*
- *Report to the USU Student Health Clinic before breakfast once during weeks 1 and 2 and twice during week 3 of each Study Period. You will need to be fasting for 10 hours. Blood will be drawn, and your blood pressure will be measured.*
- *Daily weigh-in each weekday before dinner.*
- *Provide stool samples during the last week of each Diet Period.*
- *Complete a daily compliance check list.*
- *Complete weekly questionnaires, reporting any illnesses or medication use.*
- *Consume a daily capsule containing either the drug ezetimibe, or a placebo.*
- *Consume a gelatin capsule twice daily during the last week of each Study Period.*