What are the benefits to participating?

It is not known if receiving the carnitine (L-C) therapy will result in any benefit. However, if there are benefits they may include: improvement in blood pressure, cholesterol levels, blood sugar and insulin levels, decreased thickening in your arteries, and decreased risk of death.

Your participation will contribute to the development of future life-saving treatments in the fight against heart disease.

Will I be compensated?

Parking compensation will be provided at each visit. You will receive medical care and access to clinical trial medication during this trial at no cost*. You will not be paid but there is no fee for participating.

***Access to medication depends on trial group**

Are there risks involved?

L-C is approved by Health Canada without the need for a prescription. Studies show that oral supplementation of up to 2g of L-C per day is safe, but recently concerns have been raised about effects of intestinal bacterial on L-carnitine; that's why the study is needed.

Minor side effects of L-C may include: a fishy body odour, nausea, and diarrhea. People prone to epileptic seizures should not participate.

Risks associated with blood sampling include: minor pain, bruising, and on rare occasions, infection.

What is a clinical trial?

A clinical trial is a type of medical research that compares different ways of treating patients. Most trials compare a new drug or medical approach with a treatment that is already available or with an inactive pill (placebo).

Who is conducting the ECoM trial?

Principal Investigators

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Queen's Clinical Evaluation Research Unit (CERU)

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ECoM Clinical Trial

The Effects of Carnitine Supplementation on the Progression of Carotid Plaque in Metabolic Syndrome

ECoM

Queen's University

Cardiovascular Imaging Network Queen's

robarts STROKE PREVENTION

Clinical Evaluation Research Unit

Background

In 2009, cardiovascular disease (CVD) accounted for 27% of all deaths in Canada. It is now the leading cause of death worldwide. L-carnitine (L-C) is a potential therapy that may benefit patients with CVD. It has already been shown to improve blood pressure (BP), and to promote lipid control and insulin resistance. However, its effect on the artery disease called atherosclerosis, the most important contributor to CVD, has never been studied.

What is the purpose of the EcoM trial?

To test the ability of L-C therapy, to slow down or decrease atherosclerosis, in patients with Metabolic Syndrome (MetS).

What is Metabolic Syndrome (MetS)?

MetS, considered the driving force of the new CVD epidemic, is a group of heart disease risk factors that occur together: high cholesterol, high triglycerides, obesity, diabetes, and high BP. Patients with MetS are 3 times as likely to have a heart attack or stroke and have a high risk of developing atherosclerosis.

What is Atherosclerosis?

Atherosclerosis is the thickening and narrowing of arteries due to a build-up of plaque (like scar tissue) in the walls of arteries.

What is L-Carnitine (L-C)?

L-Carnitine is an amino acid derivative naturally produced in the body. It is also present in red meat, poultry, and dairy sources. L-C plays an important role in the metabolism of blood sugar and cholesterol.

L-C supplement has U.S. Food and Drug Administration (FDA) approval for the treatment of carnitine deficiency in genetic disorders, strict vegetarians, dieters, and premature infants. Athletes use it for muscle recovery when exercising.

Who is eligible to participate?

You may be eligible to participate if you are over 18 and have at least 3 of the 5 following risk factors: elevated waist circumference (obesity), elevated fasting blood sugar (diabetes), elevated blood pressure, elevated triglycerides, or reduced HDL (low good cholesterol).

You are not eligible to participate if you have had a change in cholesterol or diabetes medication (last 3 months), are actively having unstable arrhythmia, angina, heart attack, heart failure, kidney failure, epilepsy, severe blood anomalies, endocrine disorder, severe liver problems, severe anemia, had or planning to have carotid surgery or stenting, pregnant or lactating, allergic to carnitine, or vegetarian. People who are unable to adhere to study protocol are ineligible. You cannot be on thyroid hormone, AZT, doxorubicin, isotretinoin, or valproic acid during the study period as it may interact with L-carnitine.

What will participating in this trial involve?

Screening Phase:

1. You will be assessed for inclusion criteria (age, BP, lipids, waist circumference). If you are eligible, you will be approached for informed consent, blood sampling, and 3D ultrasound (3D US) of your neck.

2. If you meet final eligibility (based on 3D US and blood tests) you will be scheduled for a second visit in which you will be randomized to the L-C therapy or placebo-control group.

Intervention Phase:

You will enter a **6-month** treatment period in which you will be provided with 2g/day (2 pills) of oral L-C or placebo to be taken twice daily.

Monitoring Phase:

During the treatment period you will attend three follow-up visits at 1, 3 and 6 months. A research coordinator will do measurements (e.g., BP, height, weight) and a doctor will assess any health issues at each visit. 3D US and blood tests will be performed at the end of the trial.

Privacy and confidentiality will be upheld at all times. You will be assigned a unique ID number during step 1 by which all data and ultrasound images will be acquired and stored.

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