Carnitine Supplementation and Skeletal Muscle Function

22/06/2015

OBJECTIVE: To evaluate the effect of carnitine supplementation as the anti-inflammatory intervention for exploring the relationship between inflammation and associated with aging reduction of skeletal muscle mass;

DESIGN: Male and female volunteers over 60 years old are recruited to participate in the study (n=40). Subjects with diabetes, liver, or renal diseases and gastro-intestinal illnesses as well as all using vitamin supplements are excluded from the study group. The patients are randomly assigned to two experimental groups (n=20). All patients are subjected to consume gelatin capsules every day throughout the study. During the 24-weeks intervention period, Group A undergoes carnitine (1.5g) supplementation, whilst group B undergoes a *placebo* supplementation. Measurements are performed before, at the mid-point, and at the end of the intervention period (see primary and secondary output variables below).

METHODS:

- *Plasma cytokines concentration* – Plasma cytokines (TNF-α, IL-1 and IL-6) as well as CRP is determined by enzyme immunoassay methods using high sensitivity commercial kits.

- *Biodex* – The maximal isometric knee extensor peak torques is determined for all subjects by using a dynamometer to evaluate the relative changes in maximal force-generating capacity over the time course of supplementation. All subjects is familiarized with the testing protocol at least 2 weeks before testing baseline muscle strength measurements. To standardize the testing, subjects will have their shoulders strapped to the chair with adjustments for the back and hips and will perform each protocol in the sitting position. Each subject will perform three repetitions for the isometric contraction, with 90 s of rest between the repetitions (the subject's knee at an angle of 70°). The highest peak torque value is considered as the maximal value after recording for all repetitions.

- *Octapolar bioimpedance analysis of body composition* – Each participant is weighted in accordance with the manufacturer's guidelines of the multifrequency analyzer. The contact with a total of 8 electrodes (2 for each foot and hand) gives the body composition analysis: dry lean mass, lean body mass, body fat mass, percent body fat and segmental lean analysis

- *Plasma FFA and glycerol* – Plasma samples is taken in fasted state before starting and after finishing the training protocol. FFA and glycerol concentrations is determined by routine enzymatic spectrophotometric assays in the laboratory of prof. A. Szutowicz.

- *Global Physical Activity Questionnaire* – Developed by WHO questionnaire for physical activity surveillance. It collects information on physical activity participation in three domains: activity at work, travel to and from places and recreational activities; as well as sedentary behaviour, comprising 16 questions.

INFORMED CONSENT FORM

Title: Carnitine supplementation and skeletal muscle function in aging
Name ....
Date of birth..... Sex .....Age .....
Address..... ....
Phone..... ....

STUDY'S PURPOSE

Carnitine is the compound responsible for the transport of fatty acids into the mitochondria - thus allowing for the modification of muscle cell metabolism. Carnitine is a dietary supplement (eating is intended to supplement the diet). Carnitine has been available on the market for several decades and there have been no side effects with its use in humans. The protocol of supplementation used in this study will be based on the procedure described in 2011 by prof. Greenhaff (UK). It will last 24 weeks. During this period, the subjects will consume up to 1.5g of carnitine a day. No side effects have been reported in the study.
This study was approved by the Independent Bioethics Committee for Research at the Medical University of Gdansk, established by the Rector of the University, on the basis of the Regulation of the Minister of Health and Social Welfare. The task of the Commission is to protect investigated rights. The head of the study is Dr. hab. Robert Olek.

PROCEDURES

The study will be conducted for a period of 26 weeks (24 weeks of supplementation, and measurements of strength and body composition prior to the start of the supplementation as well as post-supplementation regimen) from January 2016 to July 2016. During the study, fasting blood samples will be collected at 3 different days before supplementation, after 12 and 24 weeks of supplementation. The study is a double blind trial of 40 volunteers over the age of 60. In order to compare the action of carnitine research will be divided into two subgroups - one will take carnitine, the other placebo. This means that until the end of the study you will not know whether you are given carnitine or an identical looking capsule containing no carnitine. You will receive a supplement once a day after the main meal. Until the end of the research program, you will not know whether you consume carnitine or placebo. Also people who do the measurements will not know that.
In addition, before starting supplementation, after 12 and 24 weeks of supplementation, tests will be performed to determine the motor function of the elderly and to measure body weight and body fat content.

RISKS

Carnitine supplementation has already been used in many studies on humans. This type of supplementation protocol was used only once in a laboratory study in Nottingham (UK). No side effects were found
Blood samples will be taken in 8 ml volume on a follow-up visit, total 24ml in 6 months.

Blood collection is associated with a sting. If you have an inflammatory reaction, you should contact Dr. Robert Olek (505 814 645) to provide you with appropriate medical care.

POTENTIAL BENEFITS

We will thoroughly examine your state of health, sometimes using complicated and expensive methods. By identifying selected inflammatory factors, the relationship between pro-inflammatory factors and skeletal muscle function in aging will be better understood. Thus, the results of these studies can improve the health of many people, not only in Poland but around the world. During the study, you will not be able to take any dietary supplements, modify your diet or exercise your physical activity.

ADDITIONAL INFORMATION

We encourage you to ask questions about the study before and during the course. You will also receive a copy of this letter for inspection. If you have additional questions, please call 505 814 645.

PARTICIPATION

You can resign of participating in this study at any time, after notifying Dr. Robert Olek

SIGNATURES

I have read the above information. I agree to participate in the study. I received one copy of this letter.

Signature of the participant ....Date….....

I, the undersigned, fully explained all the details of this study.

Signature of researcher ....Date…..... .

Signature of the witness ....Date…….

Address and phone witness ....