Study Type: Interventional

Actual Enrollment: 205 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Double (Participant, Investigator)

Primary Purpose: Treatment

Official Title: Effects of Carnitine Supplementation on Exercise-Induced Muscle Damage: A Randomized Controlled Trial

Actual Study Start Date: May 9, 2025

Actual Primary Completion Date: May 15, 2025

Actual Study Completion Date: June 5, 2025

INFORMED CONSENT FORM

Title of the Research Project:

Investigation of the Effects of L-Carnitine Supplementation on Muscle Damage and Delayed Onset Muscle Soreness (DOMS) After High-Intensity Interval Exercise in Athletes

Name of the Principal Investigator: Res. Assist. Muhammet YILMAZ

Names of Other Investigators: Assoc. Prof. Dr. Halit HARMANCI**,** Assoc. Prof. Dr. Filiz ÖZYİĞİT

You are invited to participate in a study entitled "Investigation of the Effects of L-Carnitine Supplementation on Muscle Damage and Delayed Onset Muscle Soreness (DOMS) After High-Intensity Interval Exercise in Athletes." This study is conducted for research purposes.

Before deciding whether to participate in this study, it is important that you understand why the research is being conducted, how it will be carried out, how the information related to you will be used, what the study involves, and the possible benefits, risks, and discomforts. Please take the time to read the following information carefully and discuss it with your family and/or your physician if you wish. After you have fully understood the study and all your questions have been answered, you will be asked to sign this form if you decide to participate.

What are the aims and rationale of the study, and how many people besides me will participate?

The aim of this study is to examine the effects of L-carnitine supplementation on muscle damage and delayed onset muscle soreness (DOMS) after high-intensity interval exercise in athletes. A total of 30 university team athletes who have been actively engaged in sports for at least two months will voluntarily participate in this study. Using a randomized, double-blind, crossover study design, participants receiving L-carnitine supplementation (group LK) and those receiving carbohydrate (powdered sugar) as a placebo (group PLC) will be included. Venous blood samples will be collected from the participants before supplementation, on the 10th day of supplementation, immediately before exercise, and at 2, 24, 48, and 72 hours after exercise. In addition, perceived pain after exercise will be determined using a visual analog scale during each blood sampling session.

Based on these considerations, 25 participants are planned to be included in the study in order to adequately determine the intended effects.

Should I participate in this study? (This section will remain unchanged)

Participation in this study is entirely voluntary. If you decide to participate, this written informed consent form will be provided for you to sign. Even if you sign this form, you are free to withdraw from the study at any time without giving any reason. Refusing to

participate, withdrawing from the study, or being withdrawn from the study will not result in any penalty or loss of rights or benefits to which you are otherwise entitled.

What will happen to me if I participate in this study?

The study has a randomized, double-blind, crossover design. Participants will undergo a high-effort Wingate cycling test consisting of four 30-second repetitions separated by 4-minute rest intervals, both with L-carnitine supplementation and without L-carnitine supplementation (placebo – powdered sugar). Participants will be asked to consume the supplements provided to them three times per day at 8-hour intervals for 21 days before the exercise test. During the 21-day supplementation period, participants will be asked to avoid over-the-counter medications such as cold and flu treatments, antioxidant-containing vitamins/foods/supplements, analgesics, aspirin, or other anti-inflammatory medications. Participants will also be asked not to consume any beverages other than water for 12 hours prior to the test. Two hours before the Wingate cycling test, participants will be provided with a standard meal (sandwich) containing 206 kcal along with fruit juice containing 112 kcal.

Venous blood samples will be collected in a seated position at the following times:

- immediately before supplementation
- on the 10th day of supplementation
- immediately before exercise
- 2, 24, 48, and 72 hours after exercise

Before each blood sampling session, muscle soreness will be assessed using a visual analog scale**.** Within the scope of this study, you will participate for approximately 25 days (the duration between the pre-test and post-test sessions), except in cases of unforeseen circumstances.

All information obtained during the study will be analyzed within the country, and the results obtained will be used solely for scientific purposes**.**

What do I need to do, and what are my responsibilities?

- In order not to influence the results of the study, you must not consume any ergogenic products during the last two weeks before the study, and you must verbally confirm this.
- You must be willing to comply with the measurement sessions and rules determined by the project coordinator.
- You will be asked to consume a similar diet 24 hours before the study. On the morning of the test, you will be asked not to consume any beverages other than water. Two hours before the test, foods and beverages with the same caloric content will be provided to you.
- You will be asked not to consume alcohol or tobacco products and not to perform strenuous exercise at least 24 hours before the test.

- It is very important that you follow all instructions provided during the study as closely as possible (such as daily lifestyle considerations, post-test requirements, rest periods, nutrition, etc.).
- If you are using any medication that may put your health or the study at risk, you must inform the researchers.

What are the risks and possible discomforts of the study, and what will be done in case of possible harm?

The mitochondrial matrix is impermeable to long-chain fatty acids for beta-oxidation. Carnitine increases fatty acid oxidation, buffers intracellular acetyl-CoA formation, and thus preserves pyruvate dehydrogenase (PDH) activity. This condition may contribute to improvements in exercise performance and delay fatigue. The general aim of this study is to reduce exercise-induced muscle damage following high-intensity exercise. No serious side effects of L-carnitine supplementation have been reported. However, even though no significant risk is expected, if any harm occurs due to participation in the research, all necessary medical interventions will be provided and all related expenses will be covered.

In such cases, you and/or your relatives may contact the following persons for information:

Name-Surname: Muhammet YILMAZ / Halit HARMANCI

Phone: 0538 343 94 18 / 0551 394 91 92

What are the benefits of participating in the study?

Participating in this study will allow you to learn about the potential benefits of the dietary supplement being investigated. In addition, observing and experiencing how sports performance tests are conducted may contribute positively to your sports career.

What will happen if new information about the study becomes available? (This section will remain unchanged)

If new information related to the research becomes available that may affect your willingness to continue participating, you or your legal representative will be informed in a timely manner**.**

Can I be withdrawn from the study without my consent?

You will not be withdrawn from the study without your consent. However, if you feel unwell during the performance-based pre-test or post-test procedures, you may terminate the test at any time.

What is the cost of participating in this study? (This section will remain unchanged)

You will not incur any financial cost by participating in this study, and NO PAYMENT WILL BE MADE to you.

How will my personal information be used? (This section will remain unchanged)

The results of the research will be used for scientific and educational purposes. All information obtained from you will be used solely for research purposes, will be kept confidential, and your identity will remain protected even if the research is published. At the end of the study, you have the right to request information about these data. Monitors, auditors, the Ethics Committee, the Ministry of Health, and other relevant health authorities may have direct access to your original medical records. By signing this written informed consent form, you grant access only to the individuals and institutions mentioned above. However, your identity will remain confidential and will not be disclosed to the public, even if the research results are published.

Who can I contact for further information, assistance, or communication?

If you have any questions regarding the study method or require additional information about the study, you may contact the physician listed below 24 hours a day.

Name-Surname: Res. Assist. Muhammet YILMAZ

Role: Principal Investigator (Research Assistant)

Phone: 0538 343 94 18

Participant Statement

It has been stated that an ergogenic and experimental study will be conducted by Res. Assist. Muhammet YILMAZ, Assoc. Prof. Dr. Halit HARMANCI, and Assoc. Prof. Dr. Filiz ÖZYİĞİT. The information above regarding this study was explained to me by the person named below, and I have read all explanations in the “Informed Consent Form” presented above. After receiving this information, I was invited to participate in the study as a participant.

I have not encountered any coercion regarding my participation in the research. I understand that if I refuse to participate, this will not negatively affect my medical care. I may withdraw from the research at any time without giving any reason during the course of the project. (However, I understand that it would be appropriate to inform the researchers in advance in order not to put them in a difficult situation.)

I may also be excluded from the research by the researcher, provided that this does not harm my medical condition. I will not bear any financial responsibility for the research procedures, and no payment will be made to me.

If any health problem arises directly or indirectly as a result of the research procedures, I have been assured that all necessary medical interventions will be provided, and I will not incur any financial cost related to these interventions.

If I encounter any health problems during the research, I know that I can contact Res. Assist. Muhammet YILMAZ at 0538 343 94 18 at any time.

I fully understand all explanations provided to me. Under these conditions, I voluntarily agree to participate in this research without any pressure or coercion.

A signed copy of this form will be given to me.

Participant

Name-Surname:

Address:

Phone:

Signature:

Date:

Witness of the Interview

Name-Surname:

Address:

Phone:

Signature:

Person Interviewing the Participant

Name-Surname:

Address:

Phone:

Signature:

Date: