University of South Australia | School of Pharmacy and Medical Sciences

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Assessment of Fatty Acid/Carnitine Homeostasis in Patients with Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME)

Protocol No.: LC/12.8

This document is called a Participant Information Sheet and Consent Form. It contains a full explanation of the study you are being invited to participate in and a consent form which you will be asked to sign if you choose to take part. Before you decide to volunteer for this study you should read this information. You are invited to ask as many questions as you like before you decide whether you would like to take part or not. Participation in this study is entirely voluntary.

STUDY INVITE

You are invited to participate in a clinical research study investigating possible disturbances in the levels of fatty acids and carnitines in patients with chronic fatigue syndrome (also known as myalgic encephalomyelitis). Fatty acids and carnitines are naturally occurring compounds that are found in all mammals and have an important role in energy production. Previous research has suggested that the levels of fatty acids and carnitines in the blood of patients with chronic fatigue syndrome are different from those in healthy people.

This study is being conducted to investigate if the blood levels of fatty acids and carntines are different in patients with chronic fatigue syndrome compared to healthy subjects (Part A). In addition, a second component of this study will investigate how fats are processed by patients with chronic fatigue syndrome compared to healthy subjects (Part B). The results of this study will be used to determine the possible application of this information as a diagnostic criterion for chronic fatigue syndrome.

This research study is being conducted by researchers at the University of South Australia. This project has been reviewed and approved by the Human Research Ethics Committee of the University of South Australia.

WHAT IS INVOLVED?

The study consists of two parts: Part A and Part B. You can volunteer to take part in Part A only or both Part A and Part B.

If you choose to participate in this study, a screening medical evaluation will determine if you are suitable to take part. This will include collection of information about you, a medical history and details of any medications you are taking.

Part A

Part A of the study involves the collection of a 10mL blood sample (via needle and syringe) on a single occasion after an overnight fast (no food or drink for 8 hours; note that water is allowed). This blood sample will then be used to determine the amount of fatty acids and carnitines in plasma (a component of blood). You will also be asked to complete two questionnaires to assess your well-being (quality-of-life) and fatigue severity.

Participation in Part A is expected to take approximately 30 minutes.

Part B

Part B of the study involves the administration of a fatty acid (oleic acid) and the measurement of its breakdown products in expired air (breath). After an overnight fast, participants will be administered a single 250mg oral (i.e. by mouth) dose of oleic acid which is processed by the body and broken down into products including carbon dioxide. The oleic acid is labelled with a marker (^{13}carbon or ^{13}C) which, after the body's processing, is expelled through the breath as carbon dioxide. Breath samples will be collected prior to oleic acid administration (baseline) and then hourly for 8 hours to measure the levels of ^{13}C-labelled carbon dioxide in the breath. The results of this test provide an indication of the rate and extent by which fatty acids are processed by the body.

The oleic acid will be incorporated into a standard breakfast meal. Additional refreshments will be provided throughout the study visit.

For females of child-bearing potential, a urine pregnancy test will be conducted prior to oleic acid breath testing. Participants returning a positive pregnancy test will be excluded from participation in Part B of the study.

Participation in Part B is expected to take approximately 8 hours.

WHO CAN PARTICIPATE?

A total of 50 patients with chronic fatigue syndrome and 50 healthy subjects will be recruited for participation in Part A of the study, of which 10 patients with chronic fatigue syndrome and 10 healthy subjects will also be enrolled in Part B.

Participants must be at least 18 years of age and either:

(i) have been diagnosed by a doctor as having chronic fatigue syndrome, or
(ii) have no significant medical conditions.

For safety reasons, people who are HIV, Hepatitis B or Hepatitis C positive are excluded from participating. In addition, volunteers who have any clinically significant medical conditions that may affect study results or have taken any medication that can affect fatty acid and/or carnitine levels within 2 months prior to the study are excluded.

WHAT DO I DO IF I WOULD LIKE TO PARTICIPATE?

If you would like to participate in this study you are asked to contact the investigator (Stephanie Reuter Lange) via email (stephanie.reuterlange@unisa.edu.au) or on (08) 8302 1872. The investigator will provide you with a full explanation of the study procedures and the purpose of the study. You will be given an opportunity to ask questions and if you agree to take part in the study you will be asked to sign the enclosed consent form to indicate your willingness to participate. You will receive a copy of your signed form. You are encouraged to discuss your potential participation in this study with your family and/or friends as well as an independent person such as your General Practitioner.

WHAT IF I DON'T WANT TO PARTICIPATE OR IF I CHANGE MY MIND?

Participation in this study is voluntary. A decision not to participate will have no impact on you or your medical care.

If you decide to participate, you are free to change your mind about being in the study and may stop at any time; you are asked to inform the investigator of this decision immediately. Such a decision will not influence your medical care.

The investigator may also stop your participation in the study, with or without your consent, if she feels that it is in your best interests.

The study, or part of the study, may also be stopped at any time at the discretion of the investigator or the researchers from the University of South Australia. The study may also be stopped by the ethics committee who review the study to protect the rights and welfare of the study participants.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF PARTICIPATING?

This study is part of a research effort to develop additional information about the importance of fatty acids and carnitines in chronic fatigue syndrome and may provide benefit to others in the future. You should understand that you may not receive any medical benefit from this study.

The collection of blood samples is associated with a slight risk of bruising and infection and may cause fainting. Your blood sample will be collected by trained personnel using sterile techniques.

Oleic acid is an essential fatty acid; that is, it is important for human health but is unable to be produced by the body. It is most commonly found in olive oil, but is also present in grape seed oil, peanut oil, sesame seed oil and a number of types of nuts. The consumption of oleic acid is not associated with any known side effects. The dose of oleic acid to be administered in this study is 250 mg, this compares to a recommended daily supplement dose of 2500 mg.

The oleic acid administered within Part B of this study is labelled with ^{13}C. ^{13}C is a naturally occurring, stable isotope (variant) of carbon. These compounds are considered safe as they are NOT radioactive. The labelling of oleic acid with ^{13}C allows for the measurement of the body's processing of oleic acid. The ^{13}C administered in the study is expired as carbon dioxide in the breath within a few hours.

It is important to know that additional side effects associated with the study that are not yet known may also occur.

Participating in a clinical study may be an inconvenience in your daily life and you are asked to consider the time commitments and responsibilities in your decision to participate in this study.

Study participants will be provided with reimbursement ($20 for Part A and $100 for Part B) at the completion of the study for compensation for out-of-pocket expenses, inconvenience and time involved. If the study is terminated prior to completion, or if you withdraw or are withdrawn from the study prior to completion, then a pro-rata payment will be made.

WHAT HAPPENS TO THE INFORMATION COLLECTED ABOUT ME?

All information collected during the study will be confidential. Data will be retained on file by the University of South Australia in a locked facility for a period of 15 years, after which time it will be destroyed in a confidential manner providing data analysis and reporting of results is complete. Study data will only be accessible to researchers involved in the study.

All records containing personal information will remain confidential and no information which could lead to identification of any individual will be released. The information collected in this study may be subject to review by representatives of the independent ethics committee who approved this research and the regulatory authorities who may review this study to ensure it complies with the applicable laws.

Data from the study may be published, but participant identity will remain confidential.

WILL I RECEIVE A COPY OF THE RESULTS OF THE STUDY?

In the event that the results of the study are published in a scientific journal, participants may request to be provided with a copy of the publication.

NEED MORE INFORMATION?

If you would like any further information on this study, you should contact:

Dr Stephanie Reuter Lange
School of Pharmacy & Medical Sciences
University of South Australia
Email: stephanie.reuterlange@unisa.edu.au
Phone: (08) 8302 1872

If you have any questions about the rights of participants or if you have any ethical concerns about the study, you should contact:

Ms Vicki Allen
Executive Officer
Human Research Ethics Committee
University of South Australia
Phone: (08) 8302 3118

CONSENT TO PARTICIPATE IN THIS STUDY

I acknowledge that I have read the above information relating to this research study and I have had the purpose and details of the proposed study explained to me to my satisfaction. I have had the opportunity to ask questions about the study and have received acceptable answers. I understand the nature and the purpose of the study and agree to take part.

I confirm that I will truthfully answer all of the questions asked regarding my medical past. I agree to cooperate with the instructions for participating in this study as described above.

I understand that I may not receive any medical benefit from taking part in this study.

I understand that I can withdraw from the study at any stage and that this will not affect my medical care, now or in the future.

I understand that, while information collected during this study may be published, I will not be identified and my personal results will remain confidential.

I understand that the results of the screening evaluation will determine my eligibility for inclusion and that I may not be accepted into the study.

I state that I consent to participate in this study and that my participation is voluntary. I volunteer to take part in:

☐ Part A of the study only (blood sample)

☐ Both Part A and Part B of the study (blood sample and breath test)

_____

PARTICIPANT NAME

_____ _____

PARTICIPANT SIGNATURE DATE

I certify that I have explained the study to the patient and consider that he/she understands what is involved.

_____

INVESTIGATOR NAME

_____ _____

INVESTIGATOR SIGNATURE DATE