CONSENT TO PARTICIPATE IN RESEARCH

The University of Mississippi Medical Center

Study Title: Rapid Administration of Carnitine in Sepsis (RACE)

Principal Investigator: Dr. Alan Jones

Introduction

You/your relative or ward are being invited to be in an experimental research study, because you/your relative or ward have sepsis, a severe blood stream infection. Please ask us about anything in this document or that we tell you/your relative or ward that you/your relative or ward do not understand.

Purpose

We are doing this study to determine if one of three doses of carnitine is effective in helping people with sepsis. Carnitine is a nutrient, like a vitamin, that is in everyone's normal diet and body and it helps the cells make energy. When people get really sick, they lose carnitine in their urine and the cells have difficulty making energy.

Procedures

If you/your relative or ward agree to be in this study, you/your relative or ward will receive the standard medications used to treat sepsis. You/your relative or ward will also be randomized, by chance like the flip of a coin, to receive one of three doses of carnitine or a placebo for 12 hours. A placebo looks like the study drug but does not have medicine in it. The randomization will change during the study so that study participants will be more likely to receive the dose of carnitine that is working the best. If one of the three doses of carnitine is doing very poorly, new participants will not receive that dose of carnitine. Carnitine is approved by the Food and Drug Administration (FDA), but the way we are using it is experimental. Neither you/your relative or ward, the research team, or your/your relative's or ward's treating doctor will know if you/your relative or ward are receiving the drug or placebo.

A heart tracing (EKG) will be obtained from your/your relative's or ward's records. If you/your relative or ward do not have one, we will order one for you/your relative or ward. You/your relative or ward will not be charged for the EKG.

You/your relative or ward will have a brief physical exam at enrollment, 12 hours, 24 hours, and 48 hours.

You/your relative or ward will have a video microscopy (a video of the blood flow under the tongue) done twice. Once before and once after the carnitine or placebo is administered. This is similar to having your/your relative's or ward's temperature taken with a thermometer under your/your relative's or ward's tongue. The video is not dangerous, but some people find it mildly uncomfortable.

We will draw a total of 15 tablespoons of blood during the first 4 days of your/your relative's or ward's participation:

- 3 tablespoons before the carnitine or placebo is administered
- 3 tablespoons 12 hours after the carnitine or placebo is administered
- 3 tablespoons 24 hours after the carnitine or placebo is administered
- 3 tablespoons 48 hours after the carnitine or placebo is administered
- 3 tablespoons 72 hours after the carnitine or placebo is administered

We will use the blood to determine your/your relative's or ward's body's response to infection. We will also look at the DNA for different proteins that might affect the body's response to carnitine. In the future, some of the blood may be used to learn more about the body's reaction to infection. Some of the blood may be sent to other institutions for this testing, but no identifiable information will be sent with the samples.

We will review your/your relative's or ward's medical records from the course of your/your relative's or wards hospital stay.

In 28 days, we will contact you/your relative or ward by phone to determine your /your relative's or ward's health status. We will check the Social Security Death Index (SSDI) and medical records at 3, 6, and 12 months to see if you/your relative or ward is still alive after the study.

Your/your relative's or ward's participation in this study will last for one year.

Risks

Blood Draw:

- Pain
- Infection
- Bleeding
- Bruising

Carnitine

Likely:
- Nausea

Less Likely:
- Abdominal cramping, diarrhea, or a body odor.

Rare but Serious:
- Allergic reactions may range from minor itching to rash to major reactions, which can result in death.
- Seizure

We do not know how the body might respond to the medications or procedures used in this study. We will discuss the risks identified above with you/your relative or ward and the chances that they will happen. There may be risks that we do not know about at this time. Unknown problems, ranging from a mild inconvenience to some severe enough to result in death, may occur. If you/your relative or ward experience any problems you/your relative or ward should report them immediately to the study doctor, (Alan Jones, 601-984-4000, after hours and on weekends please call the operator at 601-984-1001 and ask for the doctor on call for Dr. Jones.)

Pregnancy

The risks of L-Carnitine to an unborn child are unknown. Women who are pregnant will not be included in this study.

Benefits

This study may or may not improve your/your relative's or ward's condition. The information gained from your/your relative's or ward/s case may benefit others with your/your relative's or ward/s condition.

Alternatives

The only alternative is for you/your relative or ward to not participate in this study. You/your relative or ward will still receive standard care for your/your relative's or ward's condition, which includes fluids and antibiotics.

L-Carnitine is experimental. This means that you/your relative or ward can only receive it by enrolling in this study.

Costs

There will not be additional costs to you/your relative or ward if you/your relative or ward participate in this study. The L-carnitine or placebo will be supplied by the emergency department at no cost to you/your relative or ward. Any tests, examinations, or other procedures that are done solely for research purposes will be paid for by research funds. Insurance companies and other third party payers will not be billed for research procedures.

The rest of the medical care that you/your relative or ward will receive in this study is considered standard care for your/your relative's or ward's situation and would be recommended whether or not you/your relative or ward participate in this study. These costs will be billed to you/your relative or ward or your/your relative's or ward's insurance carrier.

Research-related injury

In the case of injury or illness resulting from your/your relative's or ward's participation in this study, medical treatment is available to you/your relative or ward at the University of Mississippi Medical Center. You/your relative or ward will be charged the usual and customary charges for any such treatment you/your relative or ward receive.

Compensation

You/your relative or ward will not be paid for participating in this study.

Voluntary Participation

Your/your relative's or ward's participation is voluntary. If you/your relative or ward decide not to participate in this study you/your relative or ward will not suffer a penalty or loss of benefits to which you/your relative or ward are otherwise entitled.

Withdrawal

You/your relative or ward may choose to stop participation in this study at any time. If you/your relative or ward decide to withdraw, the information already collected about you/your relative or ward may still be used in this study but additional information will not be collected. Your/your relative's or ward's decision to stop your/your relative's or ward's participation will have no effect on the quality of medical care you/your relative or ward receive at the University of Mississippi Medical Center. If the study doctor decides to withdraw you/your relative or ward from the study, he may do so without your/your relative's or ward's consent.

New Information

You/your relative or ward will be told of any information we learn during your/your relative's or ward's participation in this study that may affect your/your relative's or ward's willingness to participate.

Confidentiality

Every effort will be made to keep the information we learn about you/your relative or ward private. Study personnel, the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP) and the University of Mississippi Medical Center's Institutional Review Board (IRB) and Office of Integrity and Compliance may review the study records. If study results are published your/your relative's or ward's name will not be used.

Protected Health Information

Protected health information is any personal health information through which you/your relative or ward can be identified. The Protected Health Information that will be collected includes: your/your relative's or ward/s name, medical record information, and telephone number. A decision to participate in this research means that you/your relative or ward agree to the use of your/your relative's or ward's health information for the study described in this form. This information will not be released beyond the purposes of conducting this study. The information collected for this study will be kept for 6 years after the study is complete. While this study is ongoing you/your relative or ward may not have access to the research information, but you/your relative or ward may request it after the research is completed.

Number of Participants

We expect up to 100 participants to enroll in this study at UMMC and 250 participants nationwide.

Questions

If you/your relative or ward have questions about this study please call Dr. Alan Jones at 601-984-4000. After hours and on weekends please call the operator at 601-984-1001 and ask the operator to page the doctor on call for Dr. Jones.

You/your relative or ward may discuss your/your relative's or ward's rights as a research participant with the Chairman of the University of Mississippi Medical Center's Institutional Review Board, 2500 North State Street, Jackson, Mississippi 39216;

telephone, 601 984-2815; facsimile, 601 984-2961. The Institutional Review Board is a group of people not involved with this study who have reviewed the study to protect your/your relative's or ward's rights.

You/your relative or ward will be given a copy of this consent document for your/your relative's or ward's records after it has been signed.

Statement of Participation

I/my relative or ward have been told about this study, including the experimental treatment I/my relative or ward may receive, and the possible risks and benefits. I/my relative or ward agree to participate in this study, to follow instructions, and to report any side effects to my study doctor. My/my relative's or ward's participation is voluntary and I/my relative or ward may withdraw at any time without any penalty or loss of benefits to which I/my relative or ward are entitled, including medical care at the University of Mississippi Medical Center.

By signing this form I/my relative or ward are not giving up any legal rights I/my relative or ward may have.

_____
Participant's Printed Name

_____ _____
Participant's Signature Date

_____
Name of Legally Authorized Representative
of Participant

_____ _____
Signature of Legally Authorized Representative Date
of Participant

_____
Relationship to Participant

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

I acknowledge that the participant identified above has been entered into this study, with properly obtained informed consent.

_____ _____

Signature of Principal Investigator Date