The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB23-1285
Name of Subject: _____
Medical History Number: _____

STUDY TITLE: Addressing the risk of central venous catheter infection in patients on chronic home parental nutrition support

Doctor Directing Research: Dr. Dejan Micic, MD

Address: 5841 South Maryland Ave.
MC4076
Chicago IL 60637

Telephone Number: (773) 702-6140

KEY INFORMATION

We are asking you to choose whether or not to volunteer for a research study about the effectiveness of an educational video that explains and shows how to take care of a central vein catheter when people start using it for parenteral nutrition (PN) at home. This section is to give you key information to help you decide whether to participate. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is above.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

You are being asked to take part in this research study because you have recently been prescribed Parenteral Nutrition (PN) for the first time to administer at home.

PN is a special nutritional formulation in a bag that can be given directly into your blood stream (by infusion) without the need to go into your gut first. It is a way of providing fluids, electrolytes, and nutrients when you are unable to sufficiently absorb them through your gut. To make sure people in your condition get the right amount of nutrients and liquids to maintain health and/or growth, doctors prescribe PN.

PN is given through a central catheter (a long, flexible tube inserted into a vein in your neck, chest, arm, or groin) which could increase the risk of infections in blood. This risk can be minimized by using sterile techniques to avoid any central catheter contaminations with microbes such as bacteria.

The purpose of this research is to learn the effectiveness of an educational video that explains and shows how to take care of a central catheter when people use it to administer PN at home.

If you agree to participate, you will be randomly assigned (by chance, like the toss of a coin) to either the interventional group (group1) or the control group (group 2). You will have an equal chance of being assigned to either group.

All enrolled individuals will receive standard in-person hands-on training, and written instructions on sterile techniques for catheter use as part of your standard of care (SOC).

Group 1, Interventional group: In addition to the SOC written instructions, people in the interventional group will be asked to watch an educational video about sterile techniques on how to safely handle central catheters at home for PN use. The study team will share the link to the video via email or a secure text message. This video is not a standardized video and is being used only for research purposes.

Group2 - Control group: People in the control group will be given written instructions that is part of their SOC.

In addition, individuals in both groups will be asked to complete a questionnaire at three different time points, Day 0, Week 6, and Month 6. Further details are provided below in the 'detailed consent' section.

Your participation in this research will last about six (6) months and will include one (1) visit to the study clinic, which will coincide with one of your standard of care appointments.

Please see the Detailed Consent section below for additional information.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
Your participation in this study may help you take better care of the catheter by following sterile techniques. Also, your participation will help doctors further understand how to provide better training for catheter care and potential prevention of bloodstream infections.

For a complete description of benefits, refer to the Detailed Consent Section below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
The main risk of participation is the loss of confidentiality. The study team will take care to protect the confidentiality of your data throughout the study.

As an alternate, you may decide not to take part in this study and continue your usual standard of care. For a complete description of alternate procedures, refer to the Detailed Consent Section below.

DO YOU HAVE TO TAKE PART IN THE STUDY?
Taking part in this study is voluntary. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you chose not to volunteer.

You may choose not to participate at any time during the study. You will not lose any services, benefits or rights you would normally have if you chose to leave the study. The University of Chicago/University of Chicago Medical Center will not condition (withhold or refuse) treating you on whether you sign this

Authorization or revoke your authorization at a later time. If you do not sign this form, you will not receive the research-related intervention(s).

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of the study is Dr. Micic of the University of Chicago. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his phone number is (773) 702-6140.

For questions about your rights as a research subject, please contact the University of Chicago BSD IRB at 773-702-6505.

DETAILED CONSENT

WHAT IS INVOLVED IN THE STUDY?
About 100 people will take part in this study at the University of Chicago.

Before participating in this study, you will be asked to sign and date this consent form. You will be given a copy of this signed and dated form for your records.

If you enter the study, you will get a unique participant code. This code will not contain your name or any other personal details. Only the study doctor will be able to link your unique participant code to your identity.

Study Procedures

Study Visit 1 (Day 0)
This visit will take place during one of your routine standard of care appointments.
The following study activities will be done for research study purposes and are not part of your routine care.

- Your demographics such as age, gender, race, height, and weight will be recorded.
- Your past and current medical history will be reviewed.
- Randomization: you will be randomly assigned to the interventional group or the control group. You will have an equal chance of being assigned to either group.
  - Group1 - If you are assigned to the interventional group, in addition to receiving the SOC written instructions, you will be asked to watch an educational video about sterile techniques on how to safely handle central catheters at home for PN use. You will receive a link to the educational video via email or a secure text message. You can access the video as many times as needed. The duration of the video is 17 minutes.
  - Group 2- If you are assigned to the control group, you will receive written instructions on catheter care that is part of your SOC.
- Complete questionnaire: you will be asked to complete a questionnaire called 'Central Catheter Teaching and Self-Care Initial Questionnaire' on paper during the clinic visit. It will take about 5-8 minutes to complete this questionnaire. The questionnaire will ask you to rate the usefulness of the educational material and your comfort level of catheter self-care.

Study Visit 2 (Week 6)
This visit will take place remotely, 6 weeks after Study Visit 1.

- Complete questionnaire: you will be asked to complete a questionnaire called 'Central Catheter Teaching and Self-Care follow-up Questionnaire' electronically. The study team will send a link to the questionnaire via email or a secure text 6 weeks after enrollment.

Study Visit 3 (Month 6)
This visit will take place remotely, 6 months after Study Visit 1.

- Complete questionnaire: you will be asked to complete a questionnaire called 'Central Catheter Teaching and Self-Care conclusion Questionnaire' electronically. The study team will send a link to the questionnaire via email or a secure text 6 months after enrollment.

Study Visit 4 (Month 12)

- The study doctor will review your medical and hospitalization records to collect information on positive blood culture to evaluate whether you have had a blood infection due to the catheter.

The results of this study will not be shared with you; however, the study team may provide results at the end of the study upon request.

You may decide to leave the study at any time for any reason. If you decide to withdraw from the study, please talk to your study doctor. If you leave the study, no more information about you will be collected for this study. However, all the information collected previously will still be used.

In future, identifiers associated with your data could be removed from the data. The de-identified data could then be used for future research by our research team or other researchers without notifying you or asking your permission for this use.

Other Information

Dr. Dejan Micic may decide to take you off the study without your consent if:

- You are unable to meet the requirements of the study or your medical condition changes; and
- If the study is stopped

WHAT ARE THE RISKS OF THE STUDY?

Loss of Confidentiality

Any time information is collected about you, there is a potential risk for loss of confidentiality. Please refer to the 'What About Confidentiality' section for information on what measures will be taken to protect your confidentiality.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

You may benefit from improved catheter self-care techniques, and an improved physicians' understanding of catheter associated with bloodstream infections.

The information learned from this study may benefit other individuals receiving PN in the future.

WHAT OTHER OPTIONS ARE THERE?

Participation in this study is voluntary. You may choose not to participate. The decision whether or not you wish to participate in this study will not affect your care at the University of Chicago Medical Center.

All patients receiving PN regardless of their participation in this study will receive standard in-person hands-on training on catheter use and will receive written instructions on how to safely handle central catheters at home for PN use.

WHAT ARE THE COSTS?

There will be no costs to you or your insurance company resulting from your participation in this research study. However, you or your insurance company will be responsible for costs related to your usual medical care.

WILL I BE PAID FOR MY PARTICIPATION?
You will not be paid for your participation in this study.

WHAT ABOUT CONFIDENTIALITY?
There is a risk of potential loss of confidentiality. To minimize this risk, study records that identify you will be kept confidential. Any research data kept at the University of Chicago will be stored in a locked drawer, in a locked office and entered on a password-protected, encrypted, HIPAA-compliant computer. Only study staff will have access to the data. The results from tests and procedures performed as part of this study may become part of your medical record. Any research information in your medical record will be kept indefinitely.

During this study, Dr. Micic and his research team will collect protected health information (PHI) about you for the purposes of this research. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago. The PHI consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. Some of this information will come from your medical record. The information to be used on this study includes name, medical record number, email address, telephone number, and dates (including date of birth, dates of medical procedures and tests, hospitalizations (if applicable), and dates of clinic visits). We will use these identifiers to share educational video link and questionnaires, and collect data from your medical record.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including Office of Human Research Protections (OHRP). Representatives of the University of Chicago, including the Institutional Review Board (a committee that oversees the research) and the Office of Clinical Research may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

Once information is shared outside the University of Chicago, please note that your identifiable health information may be shared with someone else. The same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your medical record. Dr. Micic is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team until completion of this study.

At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results.

Data from this study may be used in medical publications or presentations. Your name and any other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time.

WHAT ARE MY RIGHTS AS A PARTICIPANT?
If you choose to no longer be in the study and you do not want any of your future health information to be

used, you must inform Dr. Micic in writing at the address on the first page. Dr. Micic may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. Your authorization to use and disclose your health information does not have an expiration date.

CONSENT

SUBJECT
The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary, and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____
Date: _____ Time: _____ AM/PM (Circle)

PERSON OBTAINING CONSENT
I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Signature of Person Obtaining Consent: _____
Date: _____ Time: _____ AM/PM (Circle)

INVESTIGATOR/PHYSICIAN:
Signature of Investigator/Physician _____
Date: _____ Time: _____ AM/PM (Circle)