The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: SQ53 disinfectant wipes for prevention of catheter related blood stream infection in patients receiving home parenteral nutrition: A Single Blind Randomized Placebo-controlled Clinical Trial
Sponsor: JVS Product Ltd.
Principal Investigator: Donald Kirby, MD (216-444-0446)
Study Coordinator: Erin McMullen

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?

We invite you to take part in a research study because you are receiving home TPN therapy. The purpose of this study is to see if a special disinfectant wipe can decrease catheter-related bloodstream infection (CRBSI) risk.

SQ 53 ready to use wipe is an investigational (experimental) disinfectant wipe. SQ53 is a new antimicrobial solution and has been tested against a wide range of bacteria, viruses, spores and fungi. It is not approved by the Food and Drug Administration (FDA).

You will be asked to start using either SQ53 wipes or alcohol wipes daily. While participating in this study, you will follow up with Home Parenteral Nutrition (HPN) clinicians as you would normally do.

Your participation in the research will last about 12 months unless there are no meaningful outcomes on preliminary analysis at 6 months.

More detailed information can be found under the section labeled: "Information on the Research."

Why might you choose not to participate in this research study?

Although current data suggest skin reaction from SQ 53 wipe is rare, you may experience skin reactions.

More detailed information about the risks of this study can be found in the section labeled "Risks."

Why might you choose to volunteer for this study?

You may not receive direct benefit from being in this study. The information obtained from this study may help treat future patients who receive HPN and will provide important information about how well people respond to SQ53 wipes.

More detailed information about the benefits of this study can be found in the section labeled "Benefits."

What are my other choices if I do not take part in this study?
If you decide not to take part in the study, you have other choices to prevent CRBSI, which include alcohol wipe and normal saline locks.

More detailed information about the alternatives to this study can be found in the section labeled "Alternatives."

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

You are being asked to participate in a research study because you are receiving home TPN therapy. One of the major complications of long-term TPN is catheter related blood stream infection (CRBSI) due to long-term central catheter. We have used the ethanol lock therapy to prevent CRBSI, which will no longer be available due to changes in supply network. The purpose of this study is to see if a special disinfectant wipe can decrease CRBSI risk.

The special disinfectant wipe is called SQ53, which will be used to clean the catheter and your skin. SQ53 is a new antimicrobial solution and has been tested against a wide range of bacteria, viruses, spores and fungi. It is shown to be very effective in preventing CRBSI in patients in India who need long-term central catheter for TPN. It has not been approved by the US FDA for general use.

How Many People Will Take Part in this Study?

Approximately 60 people will take part in this study at Cleveland Clinic.

What is involved if you decide to take part in this research study?

If you agree to take part in this research study, you will be asked to sign this consent document.

If you decide to participate in the study, you will receive either SQ53 wipes or alcohol wipes. Although using alcohol wipe is current standard of care, you will be instructed to use alcohol wipe to clean not only the catheter end cap, but also the catheter tubing. You will be assigned to one of these two wipe groups by a process called randomization, which is a process similar to flipping a coin by chance. There will be 30 patients in each group. The wipes will be used daily, as well as, when the dressing is changed, by wiping the catheter surface and hubs for at least 15 seconds. For daily use, you will be given detailed instructions to clean the exterior and the caps of the intravenous catheters by following a sterile technique. This will be done before and after each TPN infusion. When you change your catheter dressing, which you will normally do weekly, you will use wipes to clean the catheter exit site and skin around the catheter exit site, catheter exterior and catheter caps before applying a new dressing. You will continue to use normal saline locks.

If you decide to participate in the study, one of the investigators will explain how to use the wipe that you will receive in detail. This can be done in outpatient clinic, over the phone, or inpatient setting, whichever is appropriate.

The study will be continued for about 12 months unless there are no meaningful outcomes on preliminary analysis at 6 months. The outcomes will include, CRBSI rate, admission from CRBSI, catheter exchange and adverse events.

2. ALTERNATIVES
What are the alternatives to participation in the research study?

There are other options available to you for preventing CRBSI, which include normal saline locks and alcohol wipe. Your doctor can discuss available alternatives and answer any questions you may have. Your doctor will discuss with you the risks and benefits of these alternative options.

3. RISKS
What are the risks of participating in the research study?

Skin reaction

Current data suggest skin reaction from SQ 53 wipe is rare. However, you may experience skin reaction. If you experience skin reactions, such as redness, itching, pain, swelling and irritation, to any of the ingredients in the formula, then you should tell the study doctor or his/her study staff immediately so that appropriate medical measures can be followed. If you are recruited for the study, the wipe that you received will be used on a remote site (such as forearm) first to check for skin reaction before safely used to your catheter entry site.

Other Side effects
As with all research studies, drug treatment and study procedures may involve unknown risks. All medications can have both temporary and permanent side effects and can cause unforeseen adverse reactions.

Confidentiality Risks
There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential. There will be no additional information that will be collected as a part of enrollment in the study. The patient data is already collected into a password protected HPN database as current standard of practice. This data is routinely collected and updated by HPN clinicians. When analyzing your outcomes, we will use de-identified data using a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public

Unknown Risks
There may be risks or side effects related to the study drug/device that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

4. BENEFITS
What are possible benefits of participating in the research?

You may or may not benefit from participating in this study. The information obtained from this study may help treat future patients who receive HPN and will provide important information about how well people respond to SQ53 wipes. The results of this study may be published in the scientific press. You will not be identified by these results.

5. COSTS
Are there any costs to you if you participate in this study?

There will be no additional costs to you for participation in the study. You will still need to pay for your standard of care visits, tests, regular medications and other procedures that are not associated with this study. You are responsible for paying any deductibles, copayments or co-insurance that are a normal part of your health insurance plan. If you have any questions please ask the study doctor or a member of the study staff.

6. RESEARCH RELATED INJURY
What will happen if you are injured as a result of taking part in the research?

In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic will provide appropriate medical treatment for such injury in a timely manner. Provision

of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

The study Sponsor has agreed to pay for the costs to treat a research related injury determined to be related to your participation in the Study, provided certain coverage eligibility criteria are met. The specifics of such coverage eligibility criteria for this study can be provided upon request by contacting the number below, however, some examples of such coverage eligibility criteria may include, but not be limited to, a determination that the research related injury is not: (i) a medical condition that you had before you started the study; (ii) a result of the natural progression of your disease or condition; (iii) caused by your failure to follow the study plan or the study personal's instructions; or (iv) related to temporary pain or discomfort associated with your participation in the study.

Cleveland Clinic has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for Cleveland Clinic to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other mediums without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other mediums without your express consent.

Authorization to Use/Disclose Protected Health Information

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, ***Cleveland Clinic, Attn: Dr. Donald Kirby, 9500 Euclid Avenue A5-509a, Cleveland Clinic, Ohio 44195.*** If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

Clinical Trials Language

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U. S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search the Website at any time.

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions or concerns about the research, or develop a research-related problem, you should contact Cleveland Clinic Home Nutrition Support team at 216-444-6164, Monday through Friday, between 8:00am – 4:30pm. You can also send an email to homeTPN@ccf.org. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

If you leave the study early, Cleveland Clinic may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities. You will not lose any medical benefits except for any benefits that you might have been receiving in connection with this study. If you want to stop participating in the study, please tell the study doctor. You can stop taking part in the study at any time with no need to give reasons for your decision. You will be asked to return all study wipes.

There may be other reasons to stop your participation in this study that are not known at this time. If you stop participating in the study, or the study ends, you will stop receiving the study wipes. If you discontinue treatment with the study wipes, you will be asked to continue the regular follow-up visit with HPN clinicians.

If you stop participating in the study, any personal data collected previous to your stopping may still be processed along with other data collected as part of the clinical study.

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date