Hartford HealthCare

Informed Consent for Research

6816

Principal Investigator: Lee Steere, RN
IV Therapy Services
860-972-7708

You have been asked to participate in the research study, **Randomized Prospective Clinical Study Dislodgement Infection Phlebitis Prevention Eliminating Restarts (DIPPER)**. This research study is expected to last about 3 months. You are being asked to participate because you are having a peripheral intravenous line (PIV) placed for more than 24 hours and will be admitted to an inpatient unit. PIV is the placement of a tube usually in a vein in the arm or hand using a needle. A PIV is used to deliver fluids directly into a vein. About 146 patients will be enrolled in this research study at Hartford Hospital.

This research is funded by Lineus Medical. Lineus Medical is paying Hartford HealthCare to conduct this research.

The Hartford HealthCare Institutional Review Board (IRB) has reviewed the information in this consent document and has given approval for the study doctor to do the study. An IRB is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

A. The Purpose and procedures of this research

A.1. What is the purpose of this research?

The main purpose of this study is to look at the effectiveness and safety of SafeBreak Vascular compared to not using it during intravenous (IV) treatment. IV (in a vein) tubing is sometimes pulled from a patient's arm intentionally or unintentionally which may cause infections, blockages, fluid accumulating in surrounding tissue, inflammation of veins, and having to restart the IV insertion process. We are looking to see if the study device causes any or no delay in therapy compared to not using it and if helps to avoid the possible problems mentioned above.

SafeBreak Vascular (study device) is a one piece "break-away" device that is inserted between the IV pump/bag and the tube in the patient's arm. The study device is attached to a patient's IV access site tubing. When both ends of study device are attached, a sealed connection is created that allows the flow of fluid from the patient's IV bag to the tube attached to the patient. If the IV tubing gets pulled intentionally or unintentionally with enough force, the study device separates, causing the device to split into two pieces. The separation causes a valve in each side of the device to close and block the flow of fluid from both the IV tube site and from the IV placement line. If an IV pump is in use, a blocked tube causes the alarm on the pump to sound so that a medical professional can come and investigate the problem. To restart treatment, the separated SafeBreak Vascular is removed from the line and a new SafeBreak Vascular is installed.

Below are two images of the study device. One shows the assembled study device that allows the flow of fluid. The other image shows the study device separated. The separated study device will stop the flow of fluid from either end of the detached sides.

Image 1. Assembled SafeBreak® Vascular

Image 2. Separated SafeBreak® Vascular

A.2. What procedures are involved with participation in this research study?

If you agree to participate and have signed this form, you will be placed in one of two study groups. The study group to which you are assigned will be chosen by chance (like flipping a coin); this is known as "randomization". You will have an equal chance of being placed in the group assigned to the study device or the group not assigned to the study device.

If you are placed in the study device group, your IV nurse will place the SafeBreak Vascular device during your IV placement.

If you are placed in the study group not assigned to the study device (control group), your IV placement will not include the study device.

The study team will collect information about your hospital stay for a maximum of 7 days, until you are discharged, or until your IV access is removed regardless of which group you are assigned.

Regardless of what group you are in photos will be taken of your IV at different time points during your hospital stay. The study staff will take care to make certain that there is no identifying information visible if the IV photo is on the same arm as your hospital wrist band. The photos will not identify you and they will be stored using a unique subject number. The purpose of the photos is to document correct IV placement and to monitor for any possible complications.

At the end of your participation in the study, study staff will ask you questions about your experience in this study. The questions should take less than 10 minutes to complete.

A.3. Which of these procedures is experimental?

SafeBreak Vascular is not approved by the U.S. Food and Drug Administration. Its use in this study is experimental. The randomization procedure and the collection of information by the study staff is also experimental because it would not be done if you were not participating in the study.

The use of an IV access for the treatment of your condition is standard of care and is not experimental.

A.4. Where will participation take place?

Participation will take place on inpatient units on the campus of Hartford Hospital, 80 Seymour Street, Hartford, CT.

A.5. How long will participation last?

Your participation will last up to seven 7 days while your IV is in place.

B. The possible risks, discomforts and side effects of the procedures are described below, including safeguards to be used for your protection.

SafeBreak Vascular (study device):

Risks of study device:

Less Frequent (occurring from up to 10% of the time):

- Multiple separations of the device which could result in a temporary interruption in medication administration (delay of therapy)
- IV dislodgements (IV comes out of the skin)
- IV restarts (new IV must be placed into a new vein)

Rare (occurring less than 1% of the time):

- Skin rash or irritation and/or breakdown associated with use of SafeBreak Vascular
- The study device may affect how fast the medication and/or fluids are infused
- Recoil of IV line at high velocity upon separation of the study device
- Infection in the blood stream
- Air bubble of 0.5ml (about 1/10 teaspoon) enters into the blood stream (air embolus)
- There is a rare risk of breach of confidentiality (release of information, which personally identifies you).

Potential Device Misuses

- Infusion of blood or blood products through the study device: Infusing blood through SafeBreak may result in blood cells being damaged during transfusion and the patient not receiving the correct amount of blood cells. If this occurs, an additional infusion of blood may be needed
- Failure to flow fluid through the study device before connecting it to the IV. This is also called "priming" the device: If the nurse fails to prime the device, an air embolism of 0.5mL of air may occur. This amount of air infused into an adult patient is unlikely to harm the patient.

- Use of power injection equipment with device: the device may separate when subjected to pressures associated with power injection equipment. This may cause a temporary delay in therapy and fluid being infused may contact the patient.

Not all possible effects are known. With any device, unusual, unexpected or previously unreported side effects may occur.

C. There are possible benefits to you or others to be expected from your participation in this research.

You may experience no direct benefit from your participation in the study. However, a possible benefit to you or others may be a reduction of peripheral IV (PIV) catheter mechanical complications.

D. There are alternatives to participation in this study that you should consider.

You may choose not to participate in this study without any penalty to you. If you choose not to participate, your standard of care PIV insertion will not be affected.

E. Who can you call if you have questions about this study?

You do not have to sign this consent form until all the questions you have at this time are answered. The investigator is willing to answer any questions you may have about the study procedures. Below is a list of contacts if you should have any questions about the study.

Questions about:	Contact	Phone #
the research, research-related treatments, or a research related injury	Lee Steere, RN	(860) 972-7708
your rights as a research participant	An IRB Representative	(860) 972-2893
the research in general	Vice President, Research	(860) 972-2893
a confidential issue that you would like to discuss with someone not associated with research	Patient Advocates	(860) 972-1100

F. Your participation in the research is voluntary.

You may refuse to participate, withdraw your consent, and discontinue participation in the research at any time. You may do so without penalty, or loss of benefits to which you are otherwise entitled. Your decision whether to participate will not affect your future medical care at Harford HealthCare.

You will be informed of any significant new findings, which develop during the course of this research study, which may change your decision to continue participating in this study.

G. You will not receive financial compensation for your participation in this research.

H. Your confidentiality will be guarded to the greatest extent possible.

Hartford HealthCare will protect all the information about you and your part in this study, just as is done for all patients at Hartford HealthCare. Your records will be maintained in accordance with applicable state and federal laws. However, private identifiable information about you may be used or disclosed for purposes of this research project as described in the study's authorization form.

Records of your participation in this study will be held confidential to the extent permitted by the applicable laws and regulations, and consistent with the Health Insurance Portability and Accountability Act ("HIPAA") Authorization that you will be asked to sign. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA), as well as governmental agencies in other countries where the study device may be considered for approval and the Ethics Committee/Institutional Review Board (IRB) will be able to inspect and copy confidential study specific records which identify you by name. Therefore, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. Enter "NCT04469218" to access the study. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

I. What happens if you are injured as a direct result of your participation in this research project?

In the event that you are injured as a direct result of taking part in this research, you will not be required to pay any out of pocket costs related to this injury. The study sponsor will cover costs related to an injury not covered by your insurance that is a direct result of the study, unless the injury was caused by the Hospital's deviation from the protocol, the Hospital's negligence or misconduct.

If you have medical insurance, Hartford HealthCare will collect fees for medical treatment at Hartford HealthCare from your insurance company. If you are not fully covered by insurance or uninsured, the research sponsor of the study or Hartford HealthCare will cover these expenses.

There is no plan for Hartford HealthCare to pay for your medical expenses at other hospitals or for pain and suffering, travel, lost wages, or other indirect costs of taking part in this research. You do not waive any of your legal rights by signing this informed consent document.

J. Signatures

INITIAL CONSENT:

You will be given a copy of this informed consent document to keep. By signing below, it means that you have read it, that you voluntarily agree to participate in this research, "**Randomized Prospective Clinical Study Dislodgement Infection Phlebitis Prevention Eliminating Restarts (DIPPER)**" and that you consent to the performance of the procedures listed above.

Participant's Signature | Printed name | Date

Legally Authorized Healthcare Representative | *Printed name* | *Date*

If there is no LAR, or attempts to contact the LAR have been unsuccessful, consent from the next of kin listed below may be accepted. Continuing attempts must be made to obtain consent from the LAR/patient, and documentation of this must be provided.

Next of Kin Signature | Printed name | Date

Relationship to patient:

Spouse ☐ Adult Child ☐ Parent ☐ Adult Sibling ☐

Person Obtaining Participant's Signature | Printed name | Date

Witness signature | Printed name | *Date*

(A witness is the person observing the explanation of the above information to the participant. A witness to the informed consent process is optional unless presented orally.)

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CONSENT OF THE **LAR OR HIGHEST RANKING NEXT OF KIN** FOR THE PATIENT TO CONTINUE TO BE IN THE STUDY:

This patient's Next of Kin gave his/her consent for the patient to be in this research study. This is because the patient was not able to make their own decision due to their illness and you were not present at the time of the initial consent. You have been determined to be either the patient's Legally Authorized Representative or highest ranking Next of Kin. Since the patient is still not able to provide consent at this time, you are being asked to decide whether this patient should continue to be in this study. If you agree to allow the patient to continue in the study, we will continue to follow-up with the patient to obtain consent from them if they are capable. Your decision is voluntary, this means your decision is up to you.

You have read the information in this form and someone has explained to you what study procedures will be continuing. Your questions have been answered to your satisfaction and you believe you understand all of the information about this study. You have decided to allow the patient to continue taking part in this study.

Legally Authorized Healthcare Representative Printed name Date

If there is no LAR, or attempts to contact the LAR have been unsuccessful, consent from the highest ranking next of kin listed below may be accepted. Continuing attempts must be made to obtain consent from the LAR/patient, and documentation of this must be provided.

Next of Kin Signature Printed name Date

Relationship to patient:

Spouse ☐ Adult Child ☐ Parent ☐

Person Obtaining Participant's Signature Printed name Date

Witness signature Printed name Date

(A witness is the person observing the explanation of the above information to the participant. A witness to the informed consent process is optional unless presented orally.)

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CONSENT OF THE **PATIENT** TO CONTINUE TO BE IN THE STUDY:

Your legal representative or next of kin gave his/her consent for you to be in this research study. This is because you were not able to make your own decision at the time due to your illness. Your condition has now improved, therefore you are now being asked to decide whether to continue to be in this study. Your decision is voluntary, this means your decision is up to you.

You have read the information in this form and someone has explained to you what study procedures will be continuing. Your questions have been answered to your satisfaction and you believe you understand all of the information about this study. You have decided to continue taking part in this study.

Based on the information contained in this Informed Consent Form, I voluntarily agree to continue my participation in this study.

Participant's Signature	Printed name	Date
Person Obtaining Participant's Signature	Printed name	Date
Witness signature	Printed name	Date

(A witness is the person observing the explanation of the above information to the participant. A witness to the informed consent process is optional unless presented orally.)

* Signature indicates that a signed copy of this consent form has been provided to the patient.