The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Clinical and Colonoscopy Outcomes using Pure-Vu® Cleansing System in Patients with Lower Gastrointestinal Bleeding in the Intensive Care Unit: A Prospective Pilot Study
Sponsor: The Cleveland Clinic
Principal Investigator: Brian Baggott, MD- Phone: 216-444-3992
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After hours phone contact #: Call CCF Operator at 216-444-2200 and ask for Gastroenterology fellow on-call

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 currently admitted to the hospital with bleeding likely coming from your colon. Typically, in your situation, we recommend a colonoscopy where a flexible tube with a light and camera at its tip is inserted from your anus into your colon to look for the source of bleed. For a successful exam, the standard of care is for you to consume a bowel preparation the evening prior (typically 4 liters of a bowel preparation) to cleanse your colon from stool and blood prior to the colonoscopy. The purpose of this study is to use a new cleansing device called "Pure-Vu®" and bypass the need to drink a large volume bowel preparation.

The Pure-Vu® System is a novel device that consists of a sleeve applied over the colonoscope. The device is cleared by the Food and Drug Administration (FDA). Once applied over the colonoscope, it is inserted into your colon along with the scope. The purpose of the device is to generate a pulsed vortex mixture of water and air to remove debris, stool, and blood. It also has an evacuation system that is active at the time of cleansing to evacuate colonic contents simultaneously.

Your participation in the research will last for the duration of the colonoscopy using the Pure-Vu® System. 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?

Previous research showed successful cleansing of the colon using the Pure-Vu® System. However, and theoretically, it is possible your colonoscopy using Pure-Vu® might be aborted if the endoscopist has technical difficulties navigating through your colon using the device. In that case, the endoscopist might elect to attempt removing the Pure-Vu® System and finishing the colonoscopy without it and then proceed with the standard of care procedure by taking a bowel preparation that evening in preparation for a regular colonoscopy the day after.

The risks of the procedure using the device are similar to a regular colonoscopy. In the previously published studies using the device, there has been one reported perforation (tear) in the rectum of one patient.

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?

Participating in the study will help patients with lower gastrointestinal bleed receive quicker care in the future if the results of our study are positive, and that is by bypassing the need for a bowel preparation and quicker time to colonoscopy.
If you choose to participate in the study, you may be bypassing the need to drink a large volume bowel preparation before your colonoscopy and you will instead receive two enemas and proceed directly to a colonoscopy using the Pure-Vu® System. If all goes as planned with the device, this will allow you to not have to drink a cleansing preparation and will allow you, if feasible, to receive a colonoscopy in a timely fashion.

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 do not take part in this study, you will be asked to drink a large volume bowel preparation the evening before your colonoscopy (or same day if urgent colonoscopy is needed) and you will then undergo a regular colonoscopy (without the Pure-Vu® System) at least 4 hours after bowel preparation completion or the following day.

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?

- In patients bleeding from the colon, the current guidelines recommend urgent colonoscopy should be performed within 8 to 24 hours of presentation and after the patient consumes a large volume bowel preparation to clean the colon.
- Bleeding can stop during the time you are consuming the bowel preparation. By the time we perform the colonoscopy, the bleeding lesion could have stopped bleeding and could be hard to find.
- The Pure-Vu® System is applied to the scope and allows cleansing of the colon from its contents without the need for you to consume a bowel preparation. Previous studies have shown that this system has excellent and safe results cleansing the colon.
- We are performing this study to ensure the use of the Pure-Vu® System is beneficial and adequate in lower gastrointestinal bleed. This would allow bypassing the need for you to drink a large-volume bowel preparation and will allow us to perform a colonoscopy at a shorter time interval from your admission.
- Of note, you will be sedated for the procedure according to standard of care and at your physicians' discretion depending on the severity of your illness and clinical stability.

How Many People Will Take Part in this Study?

Approximately 20 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 participate in the study, you will not be required to ingest a large volume bowel preparation prior to your colonoscopy. Instead, you will receive 2 tap water enemas 30-60 minutes before your procedure and will be asked to not eat or drink anything for at least 4 hours prior to the procedure. Right before the colonoscopy, you will receive sedation according to standard of care (general anesthesia or twilight sedation at the physicians' discretion). The colonoscopy using the Pure-vu cleansing system will then take place. The Pure-Vu® System integrates with the colonoscope and generates a pulsed vortex mixture of water and air in order to remove debris, and, an evacuation system that is active at the time of cleansing to evacuate colonic contents simultaneously. The purpose of the device is to cleanse your colon thoroughly

to find the bleeding lesion. If the bleeding lesion is found prior to reaching the proximal colon, the endoscopist may elect to finish the procedure without completing the full colonoscopy. This does not hold any negative ramifications for your care but could improve your diagnosis and outcome.

If for any reason (technical, medical, etc.), the procedure using the Pure-Vu® System is not completed or aborted, the endoscopist may attempt to complete the colonoscopy using a naked scope (no device applied). If this is not successful, you will then receive a bowel preparation according to standard of care. The standard of care colonoscopy, followed by the ingested bowel preparation, will occur after 4 hours to 24 hours following bowel preparation. The bowel preparation may be administered through a nasogastric tube if necessary.

The research team will also collect information from your medical record as follows: your date of birth, gender, ethnicity, body mass index, surgical history of the abdomen and pelvis, presenting bleeding symptoms, blood work at time of bleeding development, last dose of blood thinner used (if any), number of blood product transfused. The researchers will also collect data from your colonoscopy using the Pure-Vu® System (such as time for colonoscopy completion, findings, treatments applied).

After the procedure, a follow up visit or call will be conducted to check in on your wellbeing.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

If you elect not to participate in this research study, then you would have the standard of care prep and procedure, ie, you will need to drink a bowel preparation prior to your colonoscopy. If the colonoscopy needs to occur within hours, your doctor might need to place a tube down your nose into your stomach to administer the bowel preparation rapidly for colonoscopy to occur same day. Otherwise, you would drink the bowel preparation the evening prior and your colonoscopy will take place the next day per standard of care. You will receive sedation prior to your procedure according to standard of care (general anesthesia or twilight sedation at the physicians'discretion).

3. RISKS

What are the risks of participating in the research study?

The risks of undergoing colonoscopy using the Pure-Vu device are similar to those with a regular colonoscopy according to standard of care. Those risks include a drop in your blood pressure or oxygen levels with sedation, a reaction to the sedative you will receive prior to the procedure, very small risk of perforation and a very small risk of bleeding. Those risks will be present with regular colonoscopy as well, regardless of your participation in the study. Due to the possibility of aborting the procedure due to complication with the research device, there is a risk of delay in colonoscopy and having to repeat the process again. In addition, there is the risk of the

possibility of having to stop the procedure and complete the process without using the Pure-Vu system.

Confidentiality Risks

There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential through the use of the following safeguards: data storage in password protected computers accessible only by the research team. If you decide to be in this study, the study researchers will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be kept for the length of the study. After that time, it will be destroyed or de-identified, meaning we will replace your identifying information with 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 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?

Your participation in the study may allow you to bypass the need to ingest a large volume bowel preparation which could decrease time to colonoscopy and lead to a quicker diagnosis and treatment of the bleeding lesion if found.
Participation in this study may help to improve your condition, but it is also possible that your condition may worsen. There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study may provide information that may help other people who have a similar medical problem in the future.

5. COSTS

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

The study device and all replacements or repairs will be provided free of charge, by the sponsor, while you are participating in this study. If, in the rare case, a second colonoscopy must be performed without the use of the Pure-vu device, Motus GI has agreed to pay for that cost. All other standard of care treatment will be billed to you or your medical insurance.

6. PAYMENT

Are there any payments to you if you participate in this study?

There will be no payments to you if you participate in this study.

7. Research Related Injury

What will happen if you are injured as a result of taking part in this 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.

If you suffer a research related injury as a result of being in this study, the costs for medical treatment may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research-related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

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, Dr. Brian Baggott, 9500 Euclid Ave, A31, Cleveland, OH 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 Registration

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 Dr. Brian Baggott at 216-444-3992. During non-business hours, weekends and holidays, please contact the Cleveland Clinic operator at 216-444-2200 and ask for the Gastroenterology fellow on-call. 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.

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