**NCT03955055**

**Study Title:** A randomized comparison of early deployment of a video capsule (Endocapsule EC-10: Olympus Tokyo. Japan) in Clinical Decision Unit versus conventional work-up of hematemesis [H] and non-hematemesis gastrointestinal bleeding [NHGIB]

**Document Title:** Informed Consent Form

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**UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL**
**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

# CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**Title:** A randomized comparison of early deployment of a video capsule (Endocapsule EC-10: Olympus Tokyo. Japan) in Clinical Decision Unit versus conventional work-up of hematemesis [H] and non-hematemesis gastrointestinal bleeding [NHGIB] (H00015196)

**Sponsor:** Olympus Medical Systems

**Investigator:** Dr. David Cave

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You are being invited to take part in a research study. Someone will explain this research to you. This form helps to sum up their explanation.

## KEY INFORMATION

**You are being invited to participate in a research study** because you have shown signs of bleeding in a part of your stomach or intestines.

If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

**The main question this study is trying to answer** is see if there is a better way to diagnose and treat patients who have bleeding in their stomachs or intestines.

**If you join this research,** you will be randomly assigned (like pulling a name out of a hat) to receive either:

- Video Capsule Endoscopy as the first procedure OR
- Standard of Care

As part of the study, we will also call you at 1 month to see how you are doing. We will continue to collect information from your medical record for as long as 1 year.

**You may not want to be in this study if you are uncomfortable with:**

- The fact that neither you nor your doctor will get to pick which group you are in
- Sharing your private information with researchers

**Risks:** One risk of participating in this study is the risk of "capsule retention" which means that the video capsule does not leave the intestines and stays there. This happens in about 1% of patients, with the highest reported rate at 13% of patients who have Crohn's disease.

If we believe that your capsule may be retained for more than 2 weeks you may require an X-ray of your abdomen to confirm where the capsule is located.

We will take steps to protect your personal information. However, there is a risk of breach of confidentiality.

There may also be risks that we do not know yet.

**Benefits:**

We cannot promise any benefits if you take part in this research. There may be no direct benefit to being in this study. However, knowledge gained from this study may help others with your condition in the future.

If you are in the early capsule group, we may find the bleeding source early and this may result in you being discharged from the hospital earlier and having fewer invasive procedures.

**Alternatives:** You do not have to be in this study. If you decide not to be in the research now or later, it will not affect your usual care and it won't be held against you.

You do not have to be in this study to receive a video capsule endoscopy. If it is medically necessary for your diagnosis, it will be used after an upper endoscopy and colonoscopy have been performed and not found a source for you bleeding

**If you think you might like to participate in this research, please continue reading to learn more about the details of this study.**

## STUDY DETAILS

**Why is this research being done?**

We are doing this research to see if there is a better way to treat and diagnose patients who have bleeding in their stomachs or intestines. At this time, it is very challenging for doctors to find the source of bleeding in the intestines and often this can result in patients staying in the hospital longer and having several procedures. We plan on using a device called a Video Capsule which is a pill-sized camera which can take pictures as it travels through your stomach and intestines. The pictures are sent to a recording device through a belt that you wear around your waist. The video capsule is cleared by the FDA for use in visualizing (looking at) the small intestine and it is not experimental.

The video capsule is swallowed and there is no sedation involved. The study will randomly compare two groups: one group that has the video capsule first followed by the best single procedure to treat your bleeding and one group has a standard work up with other endoscopic procedures and a capsule study at the end, if no source of bleeding is found.

The purpose of the study is to find out if using a video capsule early in a patient's care will decrease the time spent in the hospital and the number of procedures needed to diagnose and treat patients with signs of bleeding.

**How many people will take part in this research?**

About 160 people will take part here at UMass Medical School. Medical Center

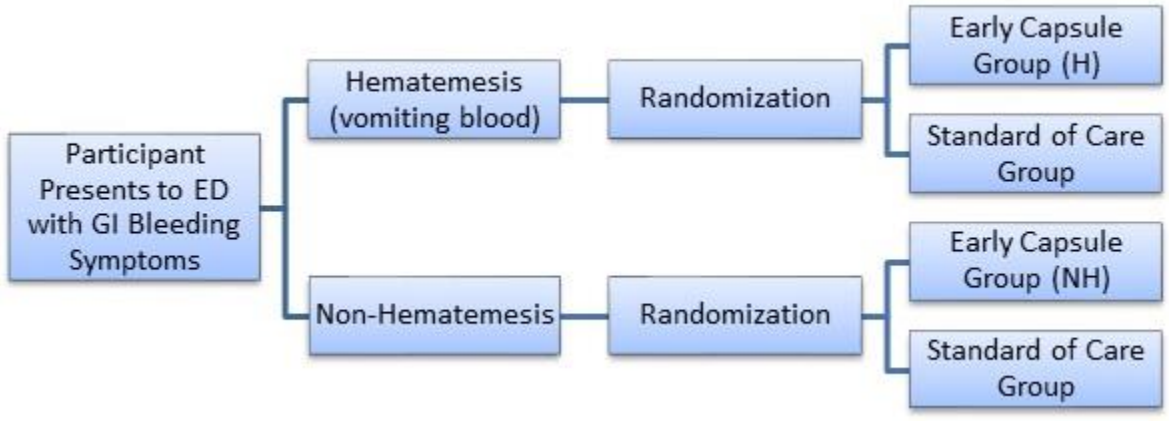
**How long will I be in this research?**

We expect that you will be in this study for 37-40 days depending on when your attending physician thinks that you will be discharged from the hospital. Usually for gastrointestinal bleeding one can expect to be in the hospital for up to 2-7 days. For this research we will be contacting you about 3 days and about 30 days after your discharge to see if you have had any further bleeding.

We will follow your care for up to 1 year by reviewing your medical record.

**What happens if I say yes, I want to be in this research?**

You will be assigned to a study arm. If you have vomited blood, you will be assigned to the Hematemesis arm. If you have passed blood through your rectum or have severe anemia (low blood count), you will be assigned to the Non-Hematemesis arm. Each arm will be assigned up to 80 participants.




Once you are assigned a study arm, you will be put into a study group by chance (like pulling names out of a hat). About 40 participants will be assigned to each group. You cannot choose your study group. The Early Capsule Group (H) and Early Capsule Group (NH) will definitely receive the capsule.

If you are randomized to the Standard of Care Groups (approximately 80 participants), you may or may not receive a video capsule depending on what your physician thinks is needed to make an accurate diagnosis. We estimate that 5% to 15% of participants (or 2 to 6 out of 40 participants) in the Standard of Care Group with rectal bleeding or anemia will receive a video capsule.

**If you are assigned to the early capsule group:**

- If you have vomited blood or passed it, you will receive the video capsule at the beginning when you come to the hospital (after you have not eaten for 10 hours). You will swallow the capsule, which sends images to a belt that you will wear around your waist. The size of the capsule is similar to a large vitamin pill. It is just over one inch long and less than ½ inch wide.


**This image is not to scale.**

- After receiving the capsule there is approximately a 1 out of 8 chance that you will require a one-time dose of a medication (either erythromycin or metoclopramide) to help the stomach move the capsule into the intestines.

- **If you have vomited blood**, once the capsule is in the small intestine the recorder will be removed and the information analyzed If you passed blood via the rectum or are anemic, the capsule will continue to record for up to 20 hours. After the video is complete, the belt will be removed, and the pictures are downloaded to make a video on a computer. The images will be reviewed to see if a bleeding site can be identified. If a bleeding site is not identified and if there is no sign of continued bleeding, and you have a stable blood pressure and blood count , your doctor may send you home, and do any necessary follow up procedures as an outpatient within 48 hours of discharge

- If you have passed blood from the rectum or have severe anemia, your doctor will be notified of the findings of your video capsule endoscopy procedure as soon as they are available and he or she will use this information in providing you with the best standard care.

- You may have additional endoscopy procedures (such as colonoscopy, upper endoscopy, or deep enteroscopy) if your doctors decide to do them as part of your care.

- The capsule will pass into your stool, usually within 24 to72 hours.

**If you are assigned to the standard of care group:**

If you have vomited blood you may have an upper endoscopy performed either as an in patient or within 48 hours as an outpatient

If you have passed blood though the rectum or are very anemic, the diagnostic tests and treatment you may receive and the length of your hospitalization, will be part of normal standard of care. You may have additional endoscopy procedures (such as colonoscopy, upper endoscopy, or deep enteroscopy) if your doctors decide to do them as part of your care. If the usual work up fails to find a source of you blood loss, you may receive the video capsule as part of your standard care.

**For all groups:**

We will collect information from your medical records about your hospitalization for research purposes. We will also be contacting you 3 days and 30 days after your discharge by telephone to see if you have had any further bleeding and whether you needed to be readmitted to the hospital. We will follow your medical records for up to 1 year.

**Will you be collecting any specimens from me?**

No.

**Could being in this research hurt me?**

Video Capsule Endoscopy

One risk of participating in this study is the risk of "capsule retention" which means that the video capsule does not leave the intestines and stays there. This happens in about 1% of patients, with the highest reported rate at 13% of patients who have Crohn's disease. Even if a capsule is "retained," it is very rare that such a complication would result in you requiring endoscopic or surgical removal. In most cases, this is the result of slow movement in your intestines and the capsule will pass naturally with more time.

If the capsule does not pass, you may require surgery. If you do require surgery, it would be to treat a condition (such as a blockage) that you already had in your intestines. This may be treated with an endoscopic procedure to dilate your intestine (using a device to widen the narrowing) or with surgery to remove part of your intestine.

If we believe that your capsule may be retained you may require an X-ray of your abdomen to confirm where the capsule is located.

Medications

Some participants will be given medications to help move the capsule from your stomach into the small intestine. There are some risks associated with these medications, which are expected to be highly unlikely as you will only have one dose. All side effects are expected to be temporary if they occur. These risks include:

- **Metoclopramide:** Rare risks include mental effects (trouble sleeping, headache, confusion), heart function abnormalities (low blood pressure, irregular heartbeat, heart

failure, blockage), and changes to hormone function (which may cause milk discharge from the breasts, lack of a menstrual period). Very rare risks include extreme changes in body temperature, uncontrollable muscle function.

- **Erythromycin:** Rare risks include gastrointestinal upset (nausea, vomiting, diarrhea, abdominal pain, lack of appetite). Very rare risks include liver function abnormalities, heart function abnormalities (abnormal heartbeat) and severe gastrointestinal problems (inflammation of the colon).

- With all medications, there is a risk of allergic reaction such as a skin rash or difficulty breathing. Your condition will be monitored closely while you are in the hospital.

Breach of Confidentiality: There is a risk that someone could get access to the data we have stored about you. If those data suggest something serious about your health, it could be misused. For example, it could make it harder for you to get or to keep a job or insurance. We believe the chance these things will happen is very small, but we cannot make guarantees.

**Will it cost me any money to take part in this research?**

You or your insurance will not have to pay for tests and procedures that are done for research purposes only (the video capsule endoscopy test). However, you or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for treating your condition. This may include the cost of tests, procedures, or medicines to manage any side effects. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.

**Will I be given any money or other compensation for being in this study?**

You will not be paid for taking part in this research.

Your research data (even if identifiers are removed) may be used to make new products, tests, or findings. These may have value and may be developed and owned by the study staff, University of Massachusetts, and/or others, including for-profit companies. If this happens, there are no plans to provide money to you.

**What happens if I am injured because I took part in this research?**

If you are injured while in the study, seek treatment and contact the study doctor as soon as you are able.

The University of Massachusetts Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

**What are my responsibilities if I take part in this research?**

If you take part in this research, you will be responsible to:

- Wear the video capsule endoscopy recording device for at least 10 hours while the video is recorded and return the equipment to the study team.

- Follow the directions of the study doctor and research staff.
- Tell your study doctor and staff about all prescriptions, over the counter medications, and vitamins or herbal supplements you are taking, and about all of your health issues.
- Tell your other health care providers that you are in a research study.

**What happens if I say yes, but I change my mind later?**

If you decide to leave this research, contact the research team so that the investigator can remove the capsule recording equipment (if you are still wearing it).

If you decide to leave the research early, there may be risks with this decision. These may include an incomplete video recording that does not record your entire small bowel.

For your safety it is important to know if the video capsule passed into your colon.

If you decide to stop, we may ask if we can contact you for safety reasons or to follow your health. We may also ask you if we can collect data from your medical records and your routine medical care.

In order to maintain the integrity of the research, data that we have already used will stay in the study database and cannot be removed.

**Can I be removed from the research without my approval?**

The person in charge of this research study can remove you even if you want to continue. This may happen if

- It is in your best interest (such as, you cannot swallow the capsule)
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- The research is canceled by the FDA or the sponsor

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

**How will my information be stored and when will it be destroyed?**

We will remove your name and any other information that could directly identify you from your data. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data.

We will keep paper documents under lock and key. We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.

There is no limit on the length of time we will store your data. We will destroy the master list of identifiers at least 6 years after completion of the study.

Identifiers might be removed from research data and be used for future research or be shared with another investigator or for-profit companies for future research, without your consent.

**Who has access to my information?**

Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

As part of the research, UMass Memorial Medical Center or any other healthcare facility where you are treated may disclose the following information:

- Demographic and identifying information like your name, date of birth, address, telephone number, and your email address
- Related medical information like family medical history, and current and past medications or therapies
- Information from physical examinations, such as blood pressure reading, heart rate, temperature, height/weight, and lab results
- All tests and procedures that will be done during your hospitalization

In the event you die while enrolled in the study, all medical records related to your treatment and death at any healthcare facility will be released to Dr. David Cave and their research staff.

Your health information and research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

- The research sponsor, Olympus Medical Systems
- People who work with the research sponsor
- Federal and state government agencies, such as the Food and Drug Administration and state auditors
- The University of Massachusetts Medical School and UMass Memorial Health Care, including the Institutional Review Board (IRB) and research, billing, and compliance offices
- Health care providers who provide services in connection with this study

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy.

Your medical record will contain a copy of this form. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

Monitors, auditors, the Institutional Review Boards, and regulatory authorities will be granted direct access to your original medical records for verification of clinical trial procedures and data without violating confidentiality.

Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. In such a case, you will not be allowed to continue to participate in the study. We will not collect any new information and may only use the information already collected for this research study. Your information may still be used and disclosed if you have an adverse event.

You do not have sign this authorization. If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

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

**Will you share any results with me?**

We can share your individual results with you if you ask. The results of the video capsule endoscopy will be shared with your care team.

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

**Who can I talk to?**

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

**Signature Block for Capable Adults**

Your signature documents your consent to take part in this research.

| | |
|---|---|
| Signature of adult research participant | Date |
| Printed name of adult research participant | |
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent | |