MEDICAL FACULTY ASSOCIATES
THE GEORGE WASHINGTON UNIVERSITY

RESEARCH CONSENT FORM

TITLE: MAGNETICALLY CONTROLLED CAPSULE FOR ASSESSMENT OF GASTRIC MUCOSA IN SYMPTOMATIC PATIENTS **(MAGNET)**

MANUFACTURER OF PILL-CAMERA: AnX Robotica
United States

PRINCIPAL INVESTIGATOR: Andrew C. Meltzer, MD
202-741-2952

STUDY-RELATED PHONE NUMBER: Andrew Meltzer, MD
202-445-7044 (24 hours)

STUDY COORDINATOR: Priscilla Muhanji
202.741.2955

KEY INFORMATION

You are being asked to take part in a research study that will test how good a remote-controlled ingestible video capsule is at viewing the inside of your stomach and looking for disease. This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process and use the contact information on this form to ask questions later.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

We are asking you to participate in this research study because you have symptoms that may be related to your stomach such as an ulcer. Currently, there is essentially one option to visualize your stomach and look for problems – a traditional endoscopy (also called "EGD") in which a patient is sedated and a "stomach doctor" (a.k.a. gastroenterologist) inserts a tube camera down your throat to take a look. Our study is trying to see if we can examine your stomach in a different way and see if this new device is just as good. The new way that we are studying this is by using a remote-controlled ingestible video capsule –a "camera pill." For this study, we hope to enroll patients for whom a traditional endoscopy is indicated but who are willing to get the "camera pill" first. The goal of this research trial is to determine if the camera-pill endoscopy is as good as the traditional endoscopy. To be in the study, you will need to have one extra clinic appointment and answer two follow-up calls within one month after your appointment.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Immediate potential benefits include an extra test to visualize problems in your stomach. In addition, we will assist you in getting your follow-up EGD as soon as possible. You will not be charged for the study and will receive $100 stipend for the extra time you have spent participating. *For a complete description of benefits, please refer to the Detailed Consent.*

WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Patients for whom study enrollment may interfere with standard clinical care will not be enrolled. Alternatives to study participation are for patient to receive standard of care treatment for symptoms, which includes only an EGD. *For a complete description of risks please refer to the Detailed Consent.*

DO YOU HAVE TO TAKE PART IN THIS STUDY?

You do not have to take part in this research. It is your choice whether or not you want to take part. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

WHAT IF YOU HAVE QUESTIONS OR CONCERNS?

The person in charge of this study is **Dr. Andrew C. Meltzer**, Principal Investigator. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is (202) 445-7044.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

Detailed Consent Form:

Study Introduction:

This consent form may contain words you do not understand. Before you decide to participate, please ask the study doctor or staff to explain anything that you do not clearly understand and take the time to discuss the study with family, friends or personal physician.

This study will test the accuracy of a single-use swallowed video capsule (NaviCam™, AnX Robotica), which is remotely controlled to view the inside of your stomach. We are asking you to participate in this research study because you have symptoms that should be evaluated by a traditional tube-based endoscope (also called "EGD"). This study is designed to enroll patients who need a traditional endoscopy but are willing to get the capsule endoscopy first as part of this research trial. The goal of this research trial is to determine if capsule endoscopy is just as good as the traditional endoscopy.

Study Summary:

- You are being asked to be in a research study and being in this study is voluntary.
- This study will test how well a capsule endoscope can visualize your stomach and identify any abnormalities.
- The capsule is controlled by an external magnet which allows it to move around your stomach and take pictures.
- After the study is completed, a "stomach doctor" (a.k.a. gastroenterologist) will review the pictures to look for disease. Because this is an experimental study, you should still get a traditional endoscopy (EGD) as soon as possible to confirm the results.
- We do not think this capsule will cause any pain or discomfort, and you should pass the capsule naturally through your stomach.

Why is this study being done?

Our primary goal is to determine whether using the video capsule will allow for visualization of the stomach for patients with symptoms that seem related to the stomach as good as traditional endoscopy.

We hope that this method will be easier, safer, than and just as accurate as traditional endoscopy (EGD).

There are many video endoscopic capsules that have been used millions of times with good safety profiles and FDA approval. What is unique about this capsule is that it is magnetically controlled to move around your stomach. This specific device has been approved by the U.S. Food and Drug Administration (FDA). We do not think that it is more risky than existing approved capsules on the market.

Will this affect my usual medical care?

If you decide not to participate in this study, it will NOT affect your ability to receive standard medical care for your condition.

The study will take place in the physician office building of the GW Medical Faculty Associates located at 2120 L Street, 2nd Floor.

If you do agree to participate, you will be scheduled for an outpatient EGD ideally within 5 business days of the capsule study. Since the follow-up EGD is considered standard of care, you or your insurance may be billed for the procedure. (However, you will NOT be billed for the capsule endoscopy procedure.)

Board-certified GI specialists will interpret both the capsule endoscopy and the traditional EGD. The results of the EGD will be shared with you as usual clinical practice and the capsule results will be available upon request.

What is involved in this study?

- The capsule endoscopy study will take place in the physician office building of the GW Medical Faculty Associates located at 2120 L Street, 2nd Floor.
- A follow-up EGD will be scheduled as soon as possible following the capsule study.
- Prior to the capsule study, we will ask you to fast overnight so that it is easier to visualize the stomach.
- You will be asked to swallow a capsule similar in size to a multi-vitamin.
- Capsule will be controlled externally by a magnetic field by the research nurse to completely visualize the stomach.
- Upon completion of the study, images and video will be stored in a server designed to maintain your privacy.
- All videos will ultimately be read by GI specialist doctors ("gastroenterologist").
- We will ask you questions regarding your experience and background.
- A day 7 and day 30 follow-up call and chart review will be conducted to check for resolution of your symptoms and side effects.

What information will be collected?

The research team will gather the following information from you or from your health care record:

- Chief complaint
- History of present illness
- Past medical history
- Medications
- Vital signs
- Tolerance of procedure
- Acceptability of this approach
- Satisfaction with experience

Follow-Up Phone Call

You will also be called on Day7 and Day 30, to see how you are doing and if you had any complications. In the case that our research team is unable to reach you at the primary phone number you provided us, we will contact your emergency contact to ask for your updated contact information to complete our follow-up.

Review of Records

You will be asked to sign a medical information release to keep on file, in the event that you are seen in another hospital facility. This will allow us to easily obtain your records for review. As part of that review, we may be reviewing date and length of hospital stay, recurrent symptoms and, if you had a repeat endoscopy.

What is the capsule endoscopy procedure?

After you swallow the capsule, it will be remotely controlled by magnetic guidance hardware. The hardware includes a magnetic guidance robot, computer workstation and software. The capsule itself is made up of a camera, an LED light source, a magnet, a wireless circuit for sending and receiving signals, and a small battery. The camera takes 2-6 pictures per second and images are sent wirelessly to the portable data recorder. Images form a video which is moved to a computer workstation from which the physician can view and assess the results. The capsule is made of biocompatible material and its internal parts are non-toxic. You do NOT return the capsule – it is disposable and used only once per person. In general, it passes in a bowel movement via natural excretion within a few days.

How many people are being enrolled in the study?

Approximately 72 subjects will be in this phase of the study.

How long will I be in the study?

The total amount of time you will spend in the clinic for the study will be 1 hour (maximum 2 hours). Overall, you will be in connection with study personnel for about one month, which includes one clinic visit to receive capsule endoscopy and two follow-up calls.

You always can choose to stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

What are the risks of the NaviCam MCC?

- The video capsule (NaviCam MCC) is manufactured by AnX Robotica and is approved by the FDA. Based on preliminary review, we believe that risks associated with this type of capsule are no different than prior capsules that have already been approved and shown to be safe. The main risk associated with this study is (1) difficulty swallowing the capsule, (2) non-natural excretion of the capsule (i.e., capsule gets stuck in the intestines). This happens in less than 1/100 patients. If you do not pass the capsule naturally through the stomach, an endoscopy (EGD) may be needed to retrieve the capsule. Given that most patients will receive an endoscopy as part of their standard work-up for the disease, the actual additional risk posed to the patient is very small.
- There is a low risk that information that we collect about you in this study may be seen by people who are not on the study team. To prevent loss of confidentiality, all data will be encrypted and no identifiable information about you will be stored with videos or other data. All study documents both electronic and hardcopy will either be locked in file drawers in the study coordinator's office or on password-protected computers.
- Patients are advised NOT to have an MRI for 30 days due to the metal contained in the capsule. For patients who are unsure whether they excreted the capsule, an abdominal X-Ray may be required as an outpatient to confirm that it has passed. If the capsule has not passed, patient should not have an MRI until further medical assessment has been performed.

- If any new information or significant findings develop during the research that may affect your willingness to be in the study, you will be informed.
- There may be risks to the study that are unknown/unforeseen.
- Reasons for not being able to participlate include the following:
    - Patient with known or suspected gastrointestinal obstruction, stenosis *(narrowing of the GI tract)* or fistula *(abnormal connection between GI tract and another anatomical site*).
    - Patient with confirmed Crohn's disease.
    - Patient implanted with a cardiac pacemaker or other implantable electronic medical device.
    - Patient implanted with an easily magnetized metal part.
    - Patient who experiences difficulty swallowing.
    - Pregnant or breastfeeding women.

Can I participate if I am pregnant?
Women who are pregnant can NOT participate in this study. A pregnancy test is standard of care in the Emergency Department for all women of childbearing age with abdominal pain.

What are the benefits of participating?
Participation in this study has limited direct benefit to you. Possible benefits are listed below:

- You may have an expedited outpatient EGD for your symptoms.
- You will have contact with the research coordinator who may assist with follow-up care and getting you access to test results.
- You will have direct access to the PI, an emergency physician and experienced researcher who will not provide medical care but can answer general questions about symptoms.
- The information from this research study may lead to a better test in the future for people with similar abdominal symptoms.

Will I be billed for participation?
There are no charges for your participation. Neither you nor your insurance will be billed for the capsule endoscopy. Standard of care procedures including follow-up EGD will be billed in the usual manner.

Will I be paid for participating?
You will receive a $100 gift card through the mail once the 30-day follow-up call has been completed for your time and effort.

Are the researchers being paid for the study?
AnX Robotica is funding the George Washington University Department of Emergency Medicine to do this study. AnX Robotica is a U.S.-based private technology company.

What are my alternatives to participating?
You do not have to be in this study to be treated for pain or other symptoms in your stomach or gut. Your alternative is to not be in this study. As part of normal standard of care, diagnostic tests may include:

- Nasogastric lavage (a thin tube that is inserted down your nose into the stomach)
- EGD – endoscopy
- Observation
- Serial Blood tests

- Barium studies
- CT Scan

The study doctor will discuss these options with you.

Will my privacy be protected?

If you are in this study, your medical records may become part of this research. They may be seen by a number of other people or groups associated with the study. Access to your study records will be limited to those who need the information for purposes of this study, as well as your health care providers if they need access to the information. All records will be kept in a secure location and access will be limited to research study personnel. The results of this research study may be presented at a scientific or medical meeting or published in scientific journals. However, your identity will not be disclosed. Except as required by law, your name, address, telephone number, or any other direct personal identifier(s) will not identify you.

Federal law requires that hospitals, researchers and other healthcare providers (like physicians and labs) protect the privacy of your health information. This section tells you about your rights regarding your health information. By signing this form and agreeing to be in this study, you are agreeing to the following uses of your health information. You are free to not allow these uses. However, if you do not allow these uses, you cannot participate in the study. Protected health information (PHI) that may be used and released (disclosed) in this study includes information such as:

- This consent form
- Demographic information (age, sex, race/ethnicity)
- Information from medical records (medications, past medical history, social history, vital signs)
- Results of physical examination
- Medical images – specifically from the pill camera and from an endoscopy
- Admission and discharge information
- Health care expenses (the cost of standard work-up)
- Questionnaires that you complete
- Laboratory blood results (blood count)
- Results of procedures

By signing this form, you allow the use, sharing, copying and release of your PHI to carry out the study by your healthcare providers and by the study doctor and his research team.

You also allow the study doctor and the research team to release your health information to:

- GWU Institutional Review Board (the "IRB") to ensure protection of the rights of research subjects
- Office of Human Research at GWU to ensure safety in research
- U.S. Food and Drug Administration FDA to review safety and effectiveness of the pill camera
- Accrediting agencies and GWU legal counsel
- Clinical staff who are not involved in the study who may become involved in your care, if it might be relevant to your care
- AnX Robotica, the manufacturer of the capsule

You may request to review or have a copy of your PHI collected during this study. This right to review and/or copy your PHI collected only extends to information that is placed in your medical record; it does not extend to information that is placed in your research record.

Your PHI will be treated confidentially to the extent permitted by applicable laws and regulations. Once your health information from this study is used or released as explained in this section, it is no longer protected by the Privacy Rule.

By signing this form, you authorize the Study Doctor and members of the research team to use and share with others (disclose) your PHI for the purpose of this study. If you do not wish to authorize the use or disclosure of your PHI, you cannot participate in this study because your PHI is necessary to conduct this study.

Do I have to give you permission to use my information? Can I change my mind?

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your PHI, you may not take part in this study because your PHI is needed in order to conduct this study.

However, you may cancel this authorization at any time. Even if you cancel this authorization, the researchers may still use the protected health information they already have collected about you. However, no new PHI will be collected from you after you cancel your permission.

This authorization does not expire unless you cancel it.

To cancel your permission, you will need to send a letter to Dr. Andrew C. Meltzer stating that you are canceling your authorization. This letter must be signed and dated and sent to this address:

Andrew C. Meltzer, MD
Department of Emergency Medicine
2120 L Street NW, Suite 450
Washington DC 20037

Who pays for my medical care if I become ill or injured because of the study?

You may have medical problems or side effects from taking part in this research study. If you have any side effects after taking the study device or are injured during the study, tell your study doctor right away. Once you tell your study doctor, he will either provide you with or refer you for proper medical treatment.

If you believed that you have been injured or have become ill from taking part in this study, you should seek medical treatment right away. This can be done through:

- GWU Hospital and/or GWU Medical Faculty Associates (MFA)
- Your physician
- The treatment center of your choice

The manufacturer of the video capsule (NaviCam MCC), AnX Robotica, will pay the reasonable medical expenses needed to treat the research-related injury or complication, including all costs associated with

removal of the video capsule, if needed, if the injury or illness is directly related to the use of the video capsule (NaviCam MCC) or the study procedures and:

- Your injury was not caused by the negligence of the study doctor or study staff; or
- Your injury was not due to a standard of care procedure that you would have undergone even if you were not participating in the study.

There are no plans for GWU, GWU Hospital and/or GWU MFA to pay for any injuries or illnesses. There are no plans to pay you for lost pay or other losses. By signing this form, you will not give up any legal rights.

Can I withdraw from the study?

Taking part in this study is voluntary. You may decide NOT to join the study. Your decision will not cause any penalty or loss of benefits to which you are entitled. If you join the study, you may decide to leave the study at any time. Again, your decision to leave will not cause any penalty or loss of benefits to which you are entitled.

Your part in this study can be stopped at any time and without your consent by the study doctor. The study doctor may stop the study at any time. This would be done for the following reasons:

- Study doctor thinks it is necessary for your health or safety;
- You do not follow study protocol
- You are unable to swallow the video capsule;
- AnX Robotica has stopped payments to support the study
- Administrative reasons require your withdrawal.

This study is registered with clinicaltrials.gov. ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by law. This website will not include information that can identify you. At most the website will include a summary of the result. You can search this website at any time.

Who do I call if I have questions or problems?

Contact Dr. Andrew C. Meltzer, Principal Investigator at 202-741-2952 or 202-445-7044, or the study coordinator, Priscilla Muhanji at 202.741.2955 for any of the following reasons:

- If you have any questions about your participation in this study.
- If you have questions, concerns or complaints about the research.
- If at any time you feel you have had a research-related injury.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact the following: GWU – Office of Human Research at telephone: 202-994-2715 or email: ohrirb@gwu.edu.

Signature Block for Adult:

By signing below, you agree that the above information has been explained to you and you have had the opportunity to ask questions. You understand that you may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research. You will receive a signed and dated copy of this consent form for your records.

_____
Subject Name (Printed)

CONSENT SIGNATURE:

_____	_____
Signature of Subject	Date
_____	_____
Print Name of Person Conducting Informed Consent	Date
_____	_____
Signature of Person Conducting Informed Consent	Date
_____	_____
Principal Investigator's Signature	Date