INVEST-REGISTRY: Minimally Invasive Endoscopic Surgical Treatment With Apollo/Artemis in Patients With Brain Hemorrhage: A Prospective Multicenter Registry

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TITLE OF RESEARCH STUDY:

Title: INVEST-REGISTRY: Minimally Invasive Endoscopic Surgical Treatment with Apollo / Artemis in Patients with Brain Hemorrhage: A Prospective Multicenter Registry

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

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WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

Basic information about this study will appear on the website http://www.ClinicalTrials.gov. There are a few reasons for this: the National Institutes of Health (NIH) encourages all researchers to post their research; some medical journals only accept articles if the research was posted on the website; and, for research studies the U.S. Food and Drug Administration (FDA) calls "applicable clinical trials" 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.

PURPOSE OF THIS RESEARCH STUDY:

You are being asked if you would like to be part of a registry. The purpose of this registry is to gather information on patients with brain bleeding that receive Minimally Invasive Endoscopic Surgical (MIES) treatment with the Apollo system or Artemis Device. This information will be reviewed as part of the process of discovering if the use of this treatment helps patients with brain bleeding to have a better outcome than those who do not use it.

All of the people who participate in the INVEST Registry will receive the MIES treatment with the Apollo system or Artemis Device at the recommendation of their doctor. The registry is simply a

means of collecting information about these people and how they recover following the procedure. Currently, MIES treatment with the Apollo system and Artemis Device is approved by FDA for intracerebral and intraventricular hemorrhage.

You may qualify to take part in this registry because you have had a stroke because of bleeding in your head. The particular type of brain hemorrhage you have had is intracerebral (ICH), intracerebral (ICH) with some intraventricular bleeding (IVH), intraventricular (IVH) with some intracerebral bleeding (ICH), or intraventricular bleeding (IVH) alone. You doctor will explain your exact situation to you in detail.

This is a very serious medical condition and the rate of death resulting from it is very high. Many of those who survive do not recover well and remain quite disabled. The amount of recovery appears to be related to the size of the blood clot that forms in the head from the bleeding episode.

Up until this time no treatment or surgery has been able to improve the results of patients who have had a bleed like this. Sometimes surgery has been done to remove clots but the procedure sometimes causes more problems than if it hadn't been done at all.

Funds for conducting this research are provided by Penumbra, Inc.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this registry is expected to last 6 months.

The maximum number of people expected to take part in this registry at Mount Sinai West is 35. The total number of people expected to take part in this registry is 50 from 30 different sites.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this registry the following information describes what may be involved. The registry procedures will take place at Mount Sinai West.

Screening

Your medical records will be reviewed. You will be asked questions about your medical history. Results of tests you have had during this hospital stay will be collected.

Baseline Evaluation

The registry doctor will examine you. The registry coordinator may also perform some neurological and functional assessments if they have not already been done. These will be explained to you before they are done. These involve observing you and asking you, or you legally authorized representative, questions about your ability to move about and take care of yourself. During this time you may have additional testing done that is part of your routine medical care. The registry team will collect the results of these tests.

If you are female and it is possible for you to become pregnant you will have a pregnancy test done. If you are pregnant, you cannot be in this registry

Standard of Care Treatment Procedure

The procedure is called Apollo / Artemis Minimally Invasive Endoscopic Surgery or Apollo / Artemis MIES. All subjects who are to receive this treatment will have the procedures described below. If you are to receive this type of treatment, you would have these procedures whether you participate in this registry or not. It has to be done within 72 hours of your symptoms of bleeding in your head. You will be placed under general anesthesia and will be asleep during the procedure.

During the procedure you will be lying on the procedure table under a sterile drape. A very small hole, called a burr hole, will be drilled through your skull.

The size of the hole may vary, but it generally is about ½ of an inch across, smaller than the size of a dime. A device called an endoscope will be placed through the hole into the area of the bleed in your brain.

The endoscope is a small telescope-like device equipped with a high-resolution video camera and eyepiece on the end to allow the doctor to find and view this area. The Apollo System is a device that is also placed with the endoscope. The combined instruments are used to rinse (irrigate) this area and to gently suction out the rinsing fluid and any blood or clot that are there.

During the procedure, you will have a CT scan performed which is part of normal standard of care for your condition. CT scans are done to see if enough of the blood and clots has been removed and also if more bleeding or problems have happened. This may be done more than once according to your doctor's discretion.

When the procedure is finished the Apollo System or Artemis Device and the endoscope are taken out of the small hole in your skull and the surgery site is closed.

You will be returned to the ICU or special stroke unit for at least 24 hours after the procedure.

24-hour follow-up

The registry doctor and/or coordinator will repeat the neurological and functional assessments that were done during your baseline evaluation to see if there have been any changes.

Your doctor will care for you according to the standard care at your hospital for people who have had similar procedures.

Discharge from the hospital or 7-day follow-up (whichever comes first)

The registry doctor and/or coordinator will examine you, repeat the neurological and functional assessments again, and review your medical record to see what complications you may have had, and what medications were given to you. You will receive information on coming for your next registry visit.

1-month follow-up, 3-month follow-up, and 6-month follow-up

At each of these standard of care follow up visits, you will also see the registry doctor and/or coordinator. You will have a physical exam and neurological and functional assessments will be done. You will be asked about any changes in your medical condition. You will be asked about what medications you are taking.

It is very important that you come to these follow-up visits.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: following your doctor's instructions and returning for routine follow-up visits.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating. All of your medical care while in the hospital will be charged to you or your medical insurance. The Apollo System or Artemis Device will also be charged to you or your medical insurance. These costs are not covered by the study. Your follow-up visits to the study team will be at no charge to you.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be that you recover better as a result of being in the registry, but this is not promised and cannot be guaranteed. The results of this registry may benefit people in the future.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

This purpose of this registry is to collect data from you and people like you who receive the MIES treatment and how you recover after the procedure. The risks involved with the INVEST Registry are only associated with data collection which is the risk of loss of private information; this risk always exists but there are procedures in place to minimize the risk.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this registry without any penalty. The choice is totally up to you.

Instead of being in this registry, your choices may include:

- Usual medical management which include the following procedures:
  - Admission to an intensive care unit or special stroke unit in the hospital;
  - Making certain the patient can breathe well, which often includes using a ventilator;
  - Managing the cause of the bleeding if it has occurred as a side effect of a medication or a medical condition that reduces the ability of the body to clot;
  - Controlling the blood pressure to keep it from getting too low or too high;

- Managing the pressure within the brain that will increase if a clot that is large takes up space, or more bleeding happens. This is done by placing a tube in part of the ventricle of the brain and allowing fluid to drain out. This is the area where cerebrospinal fluid, and not blood vessels, is located;
- If the pressure in the brain gets too high and cannot be lowered enough, brain surgery may be done to make more room for the brain swelling.

There are potential risks associated with the routine procedure. Your doctor has discussed these risks with you. Some of these potential risks are:

Likely risks:

- The radiation exposure for CT scans of the head is about 1.4 rems (14 mSv). Naturally occurring environmental radiation that happens to all people equals about 0.3 (3 mSv) per year. People who are exposed to radiation in their work often receive about 5 rems (50 mSv) per year. The amount of CT scans that you will have is up to the discretion of your doctor. They are done frequently to monitor your head to watch how the area of bleeding is doing. The CT scans performed in this study are all standard of care.

  CTA scans have about twice the amount of radiation exposure as CT scans. This amount of exposure is considered to be of a minimal risk to a patient.

- There are no known risks due to exposure to the magnetic field of a MRI scanner. However, some people are significantly bothered by the confinement to a small space (claustrophobia) and by the noise heard during the MRI scan. You will be given earplugs to wear while in the scanner.

  If you have a pacemaker or certain other implanted electronic or metallic devices, you will not have an MRI. It is important your doctor know of all devices and other metal that you may have in your body.

Less likely risks:

- Treatment with the Apollo System and Artemis Device is standard of care. The following risks are not risks of the study, but rather risks of the standard of care treatment and are being provided to you for informational purposes.
- Approximately 10-20% of patients are expected to develop infections. You will be monitored closely to watch for this. You will be treated according to the usual practice of your doctors.
- Worsening of your neurological condition.
- Sometimes (up to 24% at any time and 8-10% within the first year) patients can bleed again into their brains, either where the original bleeding happened or in a different location. As part of your usual medical care you will have CT scans, often times daily, to see if this re-bleeding has happened.
- Blood draws might cause pain and/or bruising. Some people become dizzy when they have their blood drawn and might even faint. On rare occasion someone might develop an infection where the blood is taken.

- Death.

Discomforts:

- The routine medical care while you are in the hospital, especially in the intensive care unit or special stroke unit, can result in discomforts that will vary from patient to patient. You may experience some of these.
- You might find the study follow-up visits cause you to feel tired or bored when you are being asked questions. You do not have to answer anything that you do not want to answer.

There may be side effects or discomforts that we do not already know about.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you are injured or made sick from taking part in this registry, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator Dr. Christopher Kellner for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this registry at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the registry, please contact the Principal Investigator or the registry staff. They will want to discuss this with you and resolve any issues that may be causing you to want to leave. They will also request that you come for a final follow-up visit so they can review your condition with you and thank you for your participation.

If you stop being in the registry, already collected information may not be removed from the registry study database and will continue to be used to complete the research analysis. You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this registry at any time without your consent. This may be because the registry is being stopped, the instructions of the study team have not been followed, the investigator believes it is

in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator Dr. Christopher Kellner, MD at phone number 212-241-2606.

If you experience an emergency during your participation in this research, go to the nearest hospital and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

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

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest.

Dr. Christopher Kellner (the Principal Investigator in this study), Dr. Johanna Fifi, and Reade De Leacy (Co-Investigators in this study) receive financial compensation as a lecturer, consultant, or speaker for Penumbra (the study sponsor and manufacturer of the Apollo System).

Although Dr. J. Mocco (a Co-Investigator in this study) does not receive financial compensation from Penumbra, he serves as a consultant and has ownership interest (either stocks or stock options) with companies that develop and manufacture devices for the treatment of neurologic diseases. In addition, Dr. Mocco is a manager for Neurotechnology Investors (a company which invests in start-up companies).

If you have questions regarding paid relationships that your physician/researcher may have with industry, we encourage you to talk with him or her, or check for industry relationships posted on individual faculty pages on our website at http://icahn.mssm.edu/.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be disclosed (shared) with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, dates directly related to the individual (birth, admission, discharge, date of death, etc).

The researchers will also get information from your medical record (Mount Sinai Health System or any other hospital where you have been treated, your private doctor).

During the study the researchers will gather information by:

- Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- Reviewing HIV-related information, which includes any information indicating that you have had an HIV related test, or have HIV infection, HIV related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project:
  - Other sites available on request
- Research data coordinating office and/or their representative(s) who will be responsible for collecting results and findings from all the centers: The Mount Sinai Health System
- The commercial sponsor and/or their representative (who will use the results for submissions to the Food and Drug Administration): Penumbra, Inc.
- Academic Research Organization (whose job is to help organizations fulfill their responsibilities in the research and development process): The Mount Sinai Health System
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Food and Drug Administration
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and

Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?

Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

Study ID #: GCO# 16-0028 HSM# 15-01238 **Form Version Date: 08/31/2018**

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

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Signature Block for Capable Adult

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

DO NOT SIGN THIS FORM AFTER THIS DATE → **3/28/2021**

Signature of subject	Date
Printed name of subject	Time

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

Witness Section: For use when a witness is required to observe the consent process,, document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	*Date*
Printed name of person witnessing consent process	Time