Duke University Health System

Neurocognitive Impairment Assessment in Symptomatic Carotid Occlusion Recanalized Endovascularly

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Consent to Participate in a Research Study
ADULT
Neurocognitive Impairment Assessment in Symptomatic Carotid Occlusion Recanalized Endovascularly (NIA-SCORE)

CONCISE SUMMARY

This is a research study to examine the relationship of chronically occluded internal carotid artery (ICA) and your cognition (process of thinking), memory, and mental control and self-regulation (executive function). This will be assessed by using a well-designed set of cognitive tests. In addition, we compare imaging findings with cognition, memory, mental control and self-regulation. Lastly, we are also seeking to understand whether opening the chronically occluded ICA using endovascular techniques (balloon angioplasty and stenting) will reverse the impairment of cognition, memory, mental control and self-regulation, and minimize recurrent strokes and/or transient ischemic attacks (TIAs).

You will have tests, exams and procedures that are for study purposes, such as imaging studies, physical and neurologic exams, and blood work. You will be randomized (like flipping a coin) to either surgery and opening the occluded carotid in addition to medical management or medical management alone by placing you on blood thinners and cholesterol medications.

Participation in this trial will last for 12 months. You will be asked to return to clinic for examination at 6 and 12 months and each visit will last about 2 ½ hours.

There are risks from the study drugs and procedures that are described in this document. Some risks may include: indigestion, allergic reaction, bruising, pain, redness, swelling, headache, dizziness, fatigue, muscle pain, sleep problems, low platelet counts, blood clots, infection, nerve damage, stroke, seizure, bleeding, injury to leg or kidneys, radiation exposure, and bleeding in the brain. We hope that, in the future, the information learned from this study will benefit others with your condition.

You do not have to participate in this research to be treated for your condition. Your personal healthcare provider can discuss all available options.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you have been diagnosed with complete occlusion of your cervical internal carotid artery and you have symptoms from this condition. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this

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research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. David Hasan will conduct the study and it is funded a grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. David Hasan and his research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. David Hasan will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is:
1. To examine the possible connection between long-standing blocked (or chronically blocked) internal carotid artery and your cognition (process of thinking), memory, mental control and self-regulation. This will be assessed by using a well-designed set of cognitive tests.
2. To compare findings on magnetic resonance imaging (MRI) and computerized tomography perfusion scan (CTP) on cognition, memory, mental control and self-regulation.
3. To examine whether opening the chronically blocked internal carotid artery using balloon angioplasty and stenting will reverse the impairment of cognition, memory, mental control and self-regulation.
4. To examine whether opening the chronically blocked internal carotid artery using balloon angioplasty and stenting will minimize recurrent strokes and/or transient ischemic attacks (TIAs).

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 57 people will take part in this study at two different hospitals and medical facilities, and approximately 16 people will take part at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures to make sure that you are eligible:

- Physical exam and medical history
- Vital signs
- Blood tests

If you are eligible, you will undergo the following tests and procedures:

- Neuro-cognitive Testing

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- Computerized Tomography Perfusion (CTP) to assess the blood flow in your brain
- Magnetic Resonance Imaging (MRI) spectroscopy to assess for products and size of your brain
- Brain Diagnostic Angiogram if you have not had one within the past 6 months

If you meet each criterion, you will be randomized (like flipping a coin) to:

- receive medications (aspirin, Plavix (blood thinners) and statin (cholesterol medication) only; or
- receive medications (aspirin, Plavix and statin) and undergo surgery/procedure to attempt to open the occluded carotid artery with balloon and stent

The study is open label, which means you will know which treatment you will be assigned to after randomization.

If you do not meet all the criteria for participation or you are not willing or if you are unable to be randomized to the surgery arm, you may be eligible to participate in a third group where you would receive medications (aspirin, Plavix, and statin) only.

If you are randomized to the "surgical arm" (undergo endovascular balloon angioplasty [surgical repair or unblocking of a blood vessel] and stenting), then you will have another CT perfusion done and a blood draw. If you are assigned to medications only, you will not have a second CT perfusion or blood draw.

All subjects will be asked to participate in a once monthly phone call follow up where the study team will ask how you are doing and check on your medication refills.

All subjects will be asked to return to clinic at 6 months for neurocognitive testing, another special MRI, and to check on medications.

Last visit for the study will be at 12 months. At that time, you will have repeat of the special MRI of the brain, check on medications, undergo neurocognitive testing, and have a repeat angiogram (for those randomized to surgical arm). If you did not undergo the angioplasty and you are only assigned to medication, then you will not undergo a repeat angiogram.

All of these procedures, tests, and medications are standard of care for your condition, however, the NIH grant will cover the costs of these procedures and medications.

Following this visit, you will be followed as a regular patient (according to standard of care).

Additional Information:
All MRIs preformed as part of this study can be done with oral sedative. This is done per your request on a case-by-case basis due to claustrophobia or other severe indication. If you and the PI agree that this

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would be beneficial to you, a physician that is part of the study team will order the medication for you to take before the MRI. A member of the study team will then escort you in a wheelchair to and from the MRI. You will not be permitted to drive yourself home if you are given a sedative.

COVID-19 Related Information:
If your follow up appointments occur during a COVID-19 research restriction period, your appointments may be scheduled during your clinical appointments. If this is not possible, the visits will be done via telehealth.

Detailed Description of The Procedure:
Best Medical management:
Subjects will be placed on aspirin 325 mg by mouth daily + clopidogrel (Plavix) 75 mg by mouth daily + a statin. This is the standard of care in the management of subjects with symptomatic carotid occlusion regardless of your participation in this study.

Endovascular Technique (Carotid Angiogram with Stenting):
The procedure, which is similar to an X-ray of your blood vessels, will be performed under general anesthesia. Prior to induction of general anesthesia, an arterial catheter will be paced to monitor your blood pressure. The anesthesia team will use their standard of care medications to maintain your blood pressure within standard limits.

The groin area will be prepped and draped in a sterile fashion. Femoral access (access to the femoral artery on the inner thigh) will be obtained using a needle. A plastic tube will be threaded through this needle and up into your occluded internal carotid artery. The surgical team will then attempt to open the occluded artery using balloon catheters and stents. During the procedure and for a short time afterwards, you will receive a medication that is a blood thinner, called tirofiban, to prevent clotting.

Following that, you will be transferred to surgical intensive care unit.

HOW LONG WILL I BE IN THIS STUDY?
If you agree to take part in this study, your involvement will last for 12 months. You will be asked to return to clinic for examination at 6- and 12-months post enrollment or procedure. Each visit will last about 2 ½ hours. A one-month follow-up phone call will be implemented to monitor your experiences, medications, and any adverse events between these 2 visits. You may also be contacted via email or through MyChart to remind you of upcoming visits.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

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We may learn things about you from the study activities, which could be important to your health or to your treatment. If that happens, Dr. Hasan will let you know.

WHAT ARE THE RISKS OF THE STUDY?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. These risks may be associated with the surgery, the non-surgical management of your condition, or both.

Standard of Care Medications:
Aspirin:
More Common
- indigestion and stomach aches – taking your medicine with food may help reduce this risk
- bleeding or bruising more easily than normal

Uncommon and rare
- hives – a raised, itchy rash
- tinnitus – ringing in the ears
- breathing difficulties or an asthma attack
- an allergic reaction – this can cause breathing problems, swelling of the mouth, lips or throat, and a sudden rash
- bleeding in the stomach – this can cause dark, tar-like stools or vomiting blood
- bleeding in the brain – this can cause a sudden, severe headache, vision problems and stroke symptoms, such as slurred speech and weakness on one side of the body

Clopidogrel (Plavix):
More common
- collection of blood under the skin
- deep, dark purple bruise
- itching, pain, redness, or swelling

Less common
- bloody nose
- bloody, black, or tarry stools
- vomiting of blood or material that looks like coffee grounds

Rare
- bleeding in the eye
- confusion

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- headache, sudden, severe, and continuing
- nausea and vomiting

Statin Drug (such as Lipitor or Crestor):

More Common

- headache
- dizziness
- feeling sick
- feeling unusually tired or physically weak
- digestive system problems, such as constipation, diarrhea, indigestion or gas
- muscle pain
- sleep problems
- low blood platelet count

Less Common

- memory problems
- hair loss
- pins and needles
- inflammation of the liver (hepatitis), which can cause flu-like symptoms
- inflammation of the pancreas (pancreatitis), which can cause stomach pain
- skin problems, such as acne or an itchy red rash
- sexual problems, such as loss of libido (reduced sex drive) or erectile dysfunction

Rare

- muscle weakness (myopathy)
- loss of sensation or tingling in the nerve endings of the hands and feet (peripheral neuropathy)
- tendon problems (tendons are tough cords of tissue that connect muscles to bones)

Tirofiban (Aggrastat):

More common

- bleeding
- abdominal (belly) pain or swelling
- tarry (black) stools
- blood in urine
- blood in eyes
- back, jaw, or arm pain
- bruising (purple areas) on the skin
- chest pain/tightness/discomfort/heaviness
- coughing up blood
- decreased alertness
- fast or irregular heart beat

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- headache
- joint pain or swelling
- nausea
- nose bleeds

Less common

- bleeding gums
- lightheadedness or fainting
- pinpoint red spots on the skin
- severe, unusual tiredness or weakness
- slow heartbeat
- swelling of the hands, feet, ankles, or lower legs

Rare

- chills or fever
- cough
- difficulty swallowing
- puffiness or swelling of the eyelids, or around the eyes, face, lips, or tongue
- skin rash, hives, or itching
- trouble breathing

Carotid Angioplasty and Stenting Risks: With any medical procedure, complications might happen. Here are some of the possible complications of carotid angioplasty and stenting:

- Stroke or mini-stroke (TIA): during angioplasty, blood clots that may form can break loose and travel to your brain. You will receive blood thinners during the procedure to reduce this risk. A stroke can also occur if plaque in your artery is dislodged when the catheters are being threaded through the blood vessels.
- New narrowing of the carotid artery (restenosis): a major drawback of carotid angioplasty is the chance that your artery will narrow again within months of the procedure. Special drug-coated stents have been developed to reduce the risk of restenosis.
- Blood clots: blood clots can form within stents even weeks or months after angioplasty. These clots may cause a stroke or death. It is important to take aspirin, clopidogrel (Plavix) and other medications exactly as prescribed to decrease the chance of clots forming in your stent.
- Bleeding: you may have bleeding at the site in your groin where catheters were inserted. Usually this may cause a bruise, but sometimes serious bleeding occurs and may require a blood transfusion or surgical procedures.

Reproductive Risks: Pregnancy increases the risk of blood clots, and women with vascular occlusion are strongly advised not to get pregnant because of the increased risk of complications, including maternal death. The effects of angiogram, carotid endarterectomy CT perfusion, and the standard medications on fertility and embryo development have not all been well defined. The primary obstetric

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risk with the use of clopidogrel (Plavix) is potential increased risk for intrapartum and postpartum hemorrhage. Reproductive and developmental studies in animals have not been conducted. Aspirin and tirofiban are generally not recommended during pregnancy due to increased risk of bleeding. The FDA recommends stopping statins once pregnant.

In addition, the changes your body undergoes during pregnancy may affect your recovery from surgical procedures. Angiograms and CT scanning are not often recommended in early pregnancy unless medically necessary because of potential risk to the baby. Women who are pregnant, breast-feeding, or intend to become pregnant are therefore not allowed to participate in this study.

If you are a woman who could possibly become pregnant (you have not completed menopause, or you have not had a hysterectomy and/or both tubes and/or both ovaries removed) and you have a partner who is able to father children, a blood pregnancy test will be done and it must be negative in order to continue. In women 40 years old and older, blood pregnancy tests can sometimes give a false positive or indeterminate result and additional testing may be needed to confirm your eligibility.

You and your partner must agree to either abstain completely from vaginal intercourse for the duration of the study or use an effective method of contraception for the same length of time once your study doctor informs you that it is safe to resume sexual activity. Because some birth control methods are not safe to use because of the risk of blood clots, or need to be stopped around the time of your surgery, your study doctor will discuss options with you, depending on your current method, your personal preferences, and the level of effectiveness required by this study.

Because no birth control method is 100% effective, you should notify your study doctor immediately if you think there is any chance you could be pregnant. If pregnancy is confirmed, your study doctor will help you identify a specialist in high-risk pregnancy and continue to follow you to collect information on your health during pregnancy and, if appropriate, on the health of the baby.

Risks of Radiation: Computed Tomography (CT) is a way to make x-ray images of the inside of the body. The CT scanner is a doughnut-shaped machine that uses x-rays to create computer pictures that show structures inside your body more clearly than regular x-ray pictures. During the procedure, a technologist will take you into the CT scan room where you will lie down on the patient table (usually on your back) inside of the CT machine. You should get comfortable because it is very important that you not move during certain parts of the test.

CT examinations differ depending on the part of your body being studied. For example, if your abdomen is being studied, a series of pictures will be taken from your lower chest to your lower pelvis. During the study, you will be asked to hold your breath so that the pictures will not be blurred. The machine will make some noise, and the table will move during the scan. Also, you may receive signals from the technologist or from the machine about your breathing. Before or during the study, you may be given an

injection of a contrast liquid in your vein to allow the radiologist to obtain clearer images of your organs. If you have any discomfort during the test or after the injection, be sure to tell the technologist.

Magnetic resonance imaging (MRI) uses a magnet and radio waves to make diagnostic medical images of the body. There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. However, it is possible that harmful effects could be recognized in the future. A known risk is that the magnet could attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body, including medical implants, devices such as pacemakers and internal defibrillators, or certain dyes found in tattoos. We will also keep the examining room locked so that no one carrying metal objects can enter while you are in the scanner.

If there is any question about potentially hazardous metal within your body, you will not undergo the MRI. This may exclude you from participation in this research study. The MRI involves entering a large room in which a magnet is present. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will be asked to lie still for about one hour on this bed. You will hear a loud machine-like noise. You may be asked to have a harmless monitoring device applied during the MRI. During the MRI, you can have voice contact and physical contact with someone in attendance if you desire. Let the study doctor know if you have a fear of enclosed spaces.

Risks From Imaging Tests That Use Radiation

If you take part in this research, you may have one or more CT brain perfusion scans, which use radiation. To give you an idea about how much radiation you will get each time a CT brain perfusion scan is done, we will make a comparison with an every-day situation. Everyone receives a small amount of unavoidable radiation each year called the 'natural background'. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. The chart below the amount of time in the natural background that gives an amount of radiation that is about equal to the amount of radiation each time you have the test.

A possible health problem seen with radiation exposure is the development of cancer later in life. This extra cancer risk is higher at younger ages and for girls and women. The extra lifetime risk of dying of a fatal cancer due to the radiation exposure from this research is also shown in the chart. At such low radiation exposures, scientists disagree about the amount of risk. These estimates are very uncertain, and there may be no extra risk at all.

Test	**'Natural Background Time' Equivalent for Each Time This Test is Done**	**Extra Cancer Risk Each Time This Test is Done**
CT Brain Perfusion Scan	1 Years	Very Low

If you take part in this research, you may have one or more carotid or cerebral arteriograms, which use radiation. To give you an idea about how much radiation you will get each time a carotid or cerebral

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arteriogram is done, we will make a comparison with an every-day situation. Everyone receives a small amount of unavoidable radiation each year called the 'natural background'. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. The chart below the amount of time in the natural background that gives an amount of radiation that is about equal to the amount of radiation each time you have the test.

A possible health problem seen with radiation exposure is the development of cancer later in life. This extra cancer risk is higher at younger ages and for girls and women. The extra lifetime risk of dying of a fatal cancer due to the radiation exposure from this research is also shown in the chart. At such low radiation exposures, scientists disagree about the amount of risk. These estimates are very uncertain, and there may be no extra risk at all.

Test	'Natural Background Time' Equivalent for Each Time This Test is Done	Extra Cancer Risk Each Time This Test is Done
Carotid Or Cerebral Arteriogram	2 Years	Very Low

You may have a number of medical imaging exams that are part of the regular care for your condition, and you would have them whether or not you participate in this research. These studies will not add to the risk of the research. However, if you have concerns about the overall radiation exposure, you should discuss them with your physician.

Risks From Imaging Tests That Do Not Use Radiation
You may have an MRI study as part of this research. MRI uses a magnet and radio waves to make diagnostic medical images of the body. There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. However, it is possible that harmful effects could be recognized in the future. A known risk is that the magnet could attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body, including medical implants, devices such as pacemakers and internal defibrillators, or certain dyes found in in tattoos. We will also keep the MR room locked so that no one carrying metal objects enters the room while you are in the scanner.
If there is any question about potentially hazardous metal within the body, you will not undergo the MRI. This may exclude you from participation in this research study. The MRI involves entering a large room in which a magnet is present. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will be asked to lie still for about one hour on this bed. You will hear a loud machine-like noise. You may be asked to have a harmless monitoring device applied during the MRI. During the MRI, you can have voice contact and physical contact with someone in attendance if you desire. Let the study doctor know if you have a fear of enclosed spaces.

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You may have a number of medical imaging exams that are part of the regular care for your condition, and you would have them whether or not you participate in this research. These studies will not add to the risk of the research. However, if you have concerns about the overall radiation exposure, you should discuss them with your physician.

If an oral sedative is required for your MRI(s), the following risks may be applicable to you:

- Drowsiness
- Fatigue
- Muscle weakness
- Ataxia (poor muscle control)
- Falls/Injury

Risks of Drawing Blood: Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Drug and Food Interactions: For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There may be no direct benefit to you through participation in this study. Medical management alone may or may not work for you. If you are randomized to the treatment arm, we don't know if you will benefit from the planned procedure to reopen your carotid artery in addition to routine medical management. This procedure may not reduce your risk of future stroke or improve your cognitive functions.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could only receive medications (aspirin, Plavix, and statin).

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum

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necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests, x-rays, and procedures may be reported to the NIH and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of the National Institutes of Health, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain tests, x-rays, and/or procedures performed. Some of these tests, x-rays and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the representatives and affiliates of the NIH. Results of tests and studies done solely for this research study and not as part of your regular care will also be included in your medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

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Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at Duke University Health System (DUHS). Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
You will not have any additional costs for being in this research study. The study will pay for the following:

- The clinic visits while you are enrolled in the study
- The CT perfusion at the Screening visit and the second CT perfusion while you are in the hospital if you are randomized to receive the procedure
- The magnetic resonance angiography (MRA) or computed tomography angiography (CTA) at the Screening visit
- All of the neurocognitive testing completed as part of the study
- The brain MRI at the Screening visit, 6 months, and at the 12-month visit
    - The sedative used during the MRI if you require it
- The brain diagnostic angiogram at the Screening visit if you have not had one in the previous 6 months, and again at the 12-month visit if you are randomized to receive the surgery
- All of the costs associated with the surgical procedure to open the occluded carotid artery, if you are randomized to that group

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- The laboratory tests at the Screening visit and the pre-surgical visit if you are randomized to receive the surgery
- The pregnancy test (females) at the Screening visit
- The electrocardiogram at the Screening visit
- The medications (aspirin, plavix, and statin)

You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WHAT ABOUT COMPENSATION?
If a hotel stay is required because of study visits or your surgery, you may request up to $150 for one night to subsidize cost. Additionally, you will receive $200 per completed study visit and $50 for gas for your vehicle per completed study visit.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual totals $600 or more in one calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). Research subject payments to a non-employee of Duke University adding up to $600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

No further compensation will be provided.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. David Hasan at 919-681-2512 during regular business hours and at 319-400-9455 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

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ADULT
Neurocognitive Impairment Assessment in Symptomatic Carotid Occlusion Recanalized Endovascularly (NIA-SCORE)

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Hasan in writing and let him know that you are withdrawing from the study. His mailing address is:

Dr. David Hasan
DUMC Box #3807
40 Duke Medicine Circle
Durham, NC 27710

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

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include the finding that there are no benefits from the study or there are more complications than anticipated. If this occurs, you will be notified and your study doctor will discuss other options with you.

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. David Hasan at 919-681-2512 during regular business hours and at 319-400-9455 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

Duke University Health System

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

(If applicable:)

_____	_____	_____
Signature of Legal Representative	Date	Time
_____		
Relationship to Subject		

FOR SUBJECTS WHO REGAIN THE ABILITY TO CONSENT
I have been told that my legal representative agreed for me to participate in this research. I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to continue to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____	_____	_____
Name and signature of Patient	Date	Time
_____	_____	_____
Name and signature of Person Obtaining Consent	Date	Time