

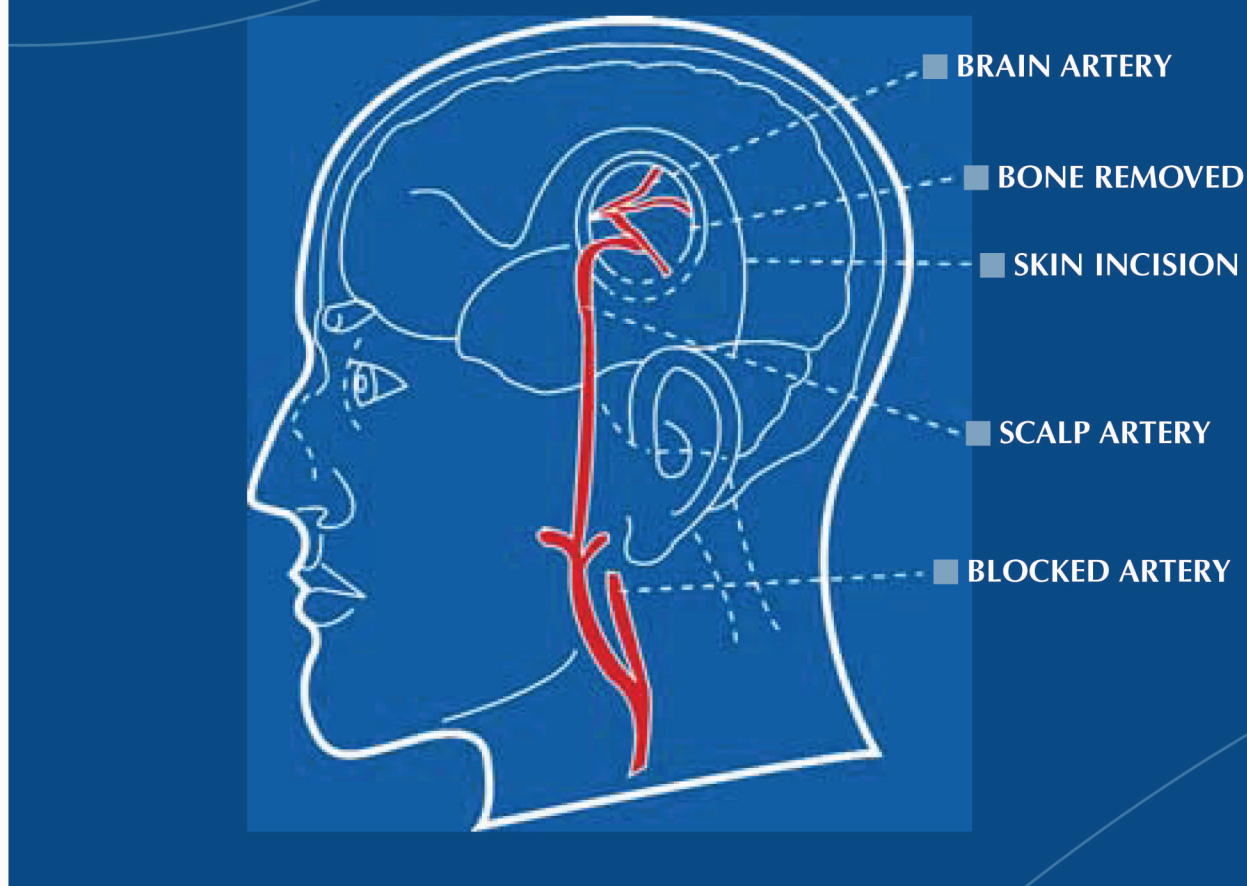
YOU MAY BE ELIGIBLE TO participate in a research study to determine if a surgical operation called “Extracranial Intracranial Bypass” can reduce the chance of a stroke in someone who has complete blockage in one main artery in the neck (the carotid artery) that supplies blood to the brain.

■ This surgery involves taking an artery from the scalp outside the skull, making a small hole in the skull, and then connecting the scalp artery to a brain artery inside the skull. In this way, the blockage of the carotid artery in the neck is bypassed and more blood can flow to the brain.

In some people, natural bypass arteries develop and the brain is already getting plenty of blood. These people have a low risk of stroke if they take medicine. In other people, no natural bypass arteries develop, so less blood flows to their brains. This second group has a much higher risk of stroke even while taking medicine, as high as 25-50% within the next two years. It is this second group of people who may benefit from having the bypass operation and who are the candidates for this study.

This bypass surgery is considered experimental because it is not generally performed for this condition and it is unknown whether it leads to a decrease, an increase or no change in

■ EXTRACRANIAL - INTRACRANIAL BYPASS



the risk of stroke. Standard medical practice at this time is to treat complete blockage of the carotid artery with medicine that reduces the risk of blood clots causing stroke.

In order to determine if you fit into this second group of people who may benefit from the bypass operation, you will need to have two tests. The first test is called a PET scan. The PET scan will measure the amount of blood that is getting to your brain and the amount of oxygen that your brain is using. The PET scan uses radioactive oxygen and water and is experimental

(not approved by the United States Food and Drug Administration). If this PET scan shows that plenty of blood and oxygen are getting to your brain, your participation in the study will be over. If the PET scan shows that less blood is getting to your brain, you may need the second test, which is called an arteriogram. An arteriogram provides a map of the blood vessels of the neck and brain to see if your arteries can be connected. This test is commonly performed on patients with stroke, and you may have already had one. If not, or if the arteriogram that you had

did not show the arteries well enough, you will need to have an arteriogram for the purpose of this study. If your arteries cannot be connected, your participation in the study will be over.

If your PET scan shows less blood getting to your brain and your arteriogram shows your arteries can be connected, you will be eligible for the study. In this case, you will have a 50-50 chance (like a coin toss) of receiving the bypass surgery. Whether you receive the bypass surgery or not, you will need to agree to return for follow-up visits to the clinic one month later and then every three months for at least two and up to six years. At each clinic visit, a medical check-up with blood tests will be performed and recommendations will be made regarding the best medicines for you to take to reduce your risk of having a stroke.

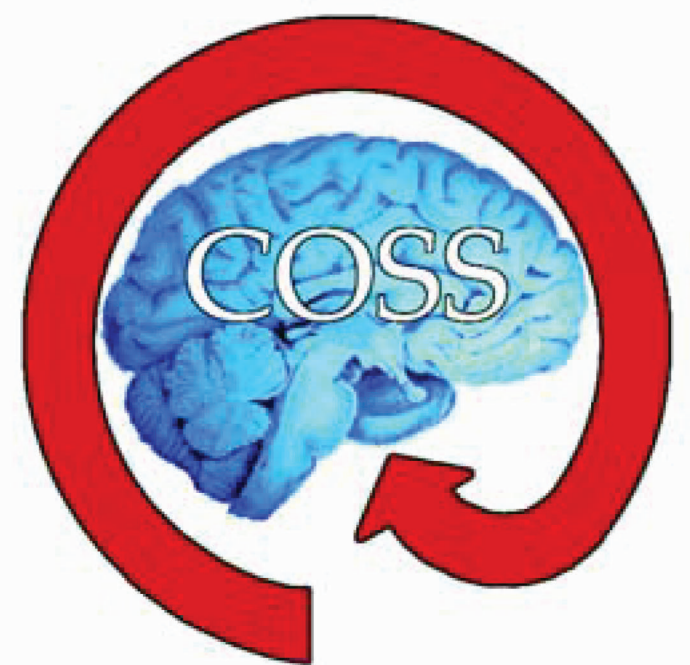
The PET scans and bypass surgery are not generally available and are not paid for by Medicare or most insurance programs. All the procedures described above (PET scans, an arteriogram, bypass surgery and medical check-ups) will be provided at no cost to you.

Your participation in this research is voluntary. You may choose not to participate in this research study or withdraw your consent at any time. Your choice will not affect the commitment of your doctors or other health care providers to administer care. There will be no penalty or loss of benefits to which you are otherwise entitled.

■ Further details and a list of participating centers may be found on the COSS web site at <http://ctsdmc.public-health.uiowa.edu/coss>

■ For further information from your local site, contact:

■ CAROTID OCCLUSION SURGERY STUDY ■



■ Funded by the National Institute of Neurological Disorders and Stroke

 **Washington University in St. Louis**
SCHOOL OF MEDICINE

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