Title: Safety and Feasibility of the Infinity Guide Catheter for Neurointerventional Procedures Using Transradial Access

NCT04553549

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Dear Patient,

Introduction and Purpose
The Rutgers Department of Neurological surgery is conducting a research study to investigate the safety and feasibility of a particular catheter, the Stryker AXS Infinity LS system, for neurointerventional procedures using the transradial approach.

Most cerebrovascular pathologies, including ischemic stroke, aneurysms, carotid stenosis, arteriovenous malformations, and brain tumors are treated through a minimally invasive endovascular approach. Historically, the right common femoral artery has been the preferred access site for these procedures. Over the last 2 decades, cardiologists have transitioned to using the radial artery for access in their procedures due to its safety as well as patient preference. Given the positive results demonstrated for cardiac interventions, the transradial approach (TRA) has emerged as a feasible alternative for neurointerventional procedures as it was demonstrated to be safer, improve patient comfort, and decrease costs and procedural time when compared to the traditional transfemoral approach (TFA).

With the preliminary experience from our own institute as well neurosurgical literature and extensive cardiology literature, we would like to conduct this study to investigate the feasibility of the AXS Infinity LS and Infinity LS plus catheters for Neuro-embolization using the TRA at our medical center. Both these catheters are FDA approved for access to the neurovasculature and they are already used routinely in the TRA at most institutions, but no formal study has been completed and reported for these two catheters.

Your participation in this study does not affect your procedure at all. Your consent allows the doctors to collect the data from your procedure in order to investigate the catheter used.

Type of Research Intervention
As previously stated, participating/not participating does NOT affect your treatment at all. Participation in the study allows the doctors to collect data from your medical record regarding the procedure for analysis.

Participant selection
You have been chosen to participate in this study because you are undergoing a neurointerventional procedure planned through the radial artery.

Voluntary Participation
Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive will continue and nothing will change. If you choose not to participate in this research project, you will still undergo the planned procedure. You may change your mind later and stop participating even if you agreed earlier.

Information on the Stryker Infinity Catheter
1) This catheter is FDA approved for use in neurointerventional procedures
2) We routinely use this catheter in neurointerventional procedures at this hospital already
3) This study simply allows us to collect the data from your case when we use this catheter

Procedures and Protocol
Participation in the study will not change the procedure performed. All patients will undergo the planned procedure using the same catheters that would be used regardless of participation. Once the procedure is completed, the patient will be admitted and monitored. At Post-operative-day 1, the radial artery is checked for patency. If there is concern the artery is not patent, an ultrasound will be performed. This procedure is repeated during your follow-up visit at about 4 weeks. In most patients, radial artery occlusion is asymptomatic.

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Risks
There are no additional clinical risks associated with participation.

Benefits
There are no direct clinical benefits to you for your participation, as the study solely involves the collection of data.

Confidentiality
The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no one, but the researchers will be able to access it. Any information about you will have a number on it instead of your name. It will not be shared with or given to anyone.

Sharing the Results
The data collected during this research will be analyzed and shared with the neurosurgical and medical community.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Whom to Contact
If you have any questions about the study you are free to contact the Principal Investigator:

Priyank Khandelwal, MD
Rutgers New Jersey Medical School
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Newark, NJ 07103
Phone (973) 972-2323

If you have any questions about your rights as a research subject, you may contact:
IRB Chair
Rutgers-Newark Campus
(973) 972-3608

Sincerely,

Priyank Khandelwal, MD
Assistant Professor of Neurological Surgery
New Jersey Medical School