

Scott & White Hospital & Clinics

Clinical Research at Scott & White

Study Title: A Prospective, Multi-Center, Randomized Study of Aqueous Oxygen Therapy for 90 minutes in Anterior Acute Myocardial Infarction subjects with Successful Reperfusion (via PCI) < Six Hours after Symptom Onset

Project ID#: 060430

Department: Cardiology

Sponsor: N/A

Brief Synopsis of the Study

You have been asked to participate in this study because you have had a heart attack (lack of oxygen to the heart muscle) and will be undergoing a coronary angiogram, which is a procedure to visualize the blood vessels of your heart using contrast dye and fluoroscopy (x-rays). You will possibly undergo angioplasty/PCI (percutaneous coronary intervention) with or without placement of a stent (small, metal, slotted tube) which are procedures to open a blocked blood vessel in your heart.

The purpose of this research study is to determine whether AO Therapy, administered (given) following PCI and stent placement, improves the function of the heart after a heart attack by reducing the amount of the heart muscle affected by the heart attack.

During your heart attack, blood flow to one or more of your coronary arteries (heart blood vessels) was reduced or stopped. When this happened, muscle cells in the heart became ischemic (starved for blood and oxygen), potentially damaging your heart. In this study we are assessing a new type of treatment that delivers oxygen-enriched blood to your heart. Two investigational (research) devices are used for AO Therapy: 1) The AO System is a medical device that controls the production (creation of) and delivery of the AO solution; and 2) the AO Cartridge is the disposable (throw away) component (part) that works with the AO System to create the AO solution, mix the AO solution with your own blood to increase the oxygen content, and deliver the oxygen-enriched blood to your heart.

Subjects will be randomized (selected by chance, like the flip of a coin) into two groups: an AO therapy subject group and control subject group ('control' means that this group will not receive the experimental study treatment). The groups are described below. There will be approximately 3 AO Therapy subjects for every 1 control subject in the research study. There may be up to 20 additional subjects treated as run-in AO Therapy subjects not randomized into either of the patient groups noted above.

Who is eligible to participate in the study?

Patients having an acute anterior MI that began within the last 6 hours.

What may be involved/required for subject participation? (Visits, tests and/or logs, etc.)

Your participation in the study will be for twelve (12) months after your enrollment to include 1 visit at Day 14 for a resting nuclear cardiology scan of your heart, 1 visit at Day 30 for an office visit and 2 telephone calls – at 6 months and 12 months.

For More Information Contact:

Coordinator: Lydia Clipper, RNC
Title: Clinical Research Coordinator
E-mail: lclipper@swmail.sw.org
