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NEWS

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Saint Luke's selected for heart valve study

Study to determine lowest levels of safe and effective anticoagulation therapy

KANSAS CITY, Mo. – Saint Luke's Mid America Heart Institute has been selected as a study site for a prosthetic heart valve that could require reduced post-surgical anticoagulation (blood thinning) therapy.

The Prospective Randomized On-X Prosthetic Heart Valve Anticoagulation Clinical Trial (PROACT), sponsored by On-X Life Technologies, is the first FDA trial to explore lower anticoagulation with mechanical heart valves.

If successful, On-X valve recipients may be able to take a lower level of anticoagulant, which would reduce the potential incidence of bleeding complications caused by taking the higher dosages of Coumadin (warfarin) normally prescribed after receiving a mechanical heart valve.

"Recent clinical evidence suggests that patients implanted with the On-X heart valve may be able to forego or reduce the dosages of anticoagulation therapy traditionally required by mechanical heart valve patients," said cardiac surgeon Keith Allen, M.D., clinical trial site investigator at Saint Luke's.

When heart valve disease progresses to the point that treatment by medicines does not provide relief from a patient's symptoms, surgery to repair or replace the valve becomes the best alternative. If the surgery is not a repair, the choice is most likely between carbon-based mechanical valves and biological tissue valves. Many factors are considered when choosing between a tissue and mechanical valve. Presently accepted mechanical valve post-operative care mandates high levels of anticoagulation therapy, which is associated with bleeding problems varying from minor to major episodes.

"This is an exciting study because it means the On-X valve could be the first prosthetic heart valve to combine the durability of mechanical valves with the reduced complication rates of tissue valves. That's considered the 'holy grail' for cardiac surgeons implanting heart valves – a valve for life," Dr. Allen said.

Tissue valves, harvested from pig or cow hearts, typically have an eight-to-15-year lifetime and require eventual replacement. They produce fewer bleeding problems with reduced anticoagulation therapy. Mechanical valves tend to be more durable, particularly in younger patients, but require anticoagulation therapy with regular monitoring.

The American Heart Association reports that 95,000 surgeries were performed in the U.S. to repair or replace malfunctioning or diseased heart valves in 2003. Cardiovascular disease is the number one cause of death worldwide.

Up to 1,200 patients for the trial are being recruited at 38 centers nationally. Additional information about the trial is available at www.clinicaltrials.gov or by calling Saint Luke's at (816) 932-6053.

About On-X Life Technologies

On-X Life Technologies designs, tests, manufactures, and markets heart valve prostheses. The On-X valve has design and material features that indicate that it may function well at lower levels of blood thinning medications. With its unique medical-grade carbon design, the On-X valve treats blood more like a natural valve and produces less turbulence, which significantly reduces the potential for life-threatening blood clots. For more information, visit www.onxlti.com

Saint Luke's Mid America Heart Institute is a member of Saint Luke's Health System, which consists of 11 area hospitals and many primary care practices, and provides a range of inpatient, outpatient, and home care services. Founded as a faith-based, not-for-profit organization, our mission includes a commitment to the highest levels of excellence in health care and the advancement of medical research and education. The health system is an aligned organization in which the physicians and hospitals assume responsibility for enhancing the physical, mental, and spiritual health of people in the metropolitan Kansas City area and the surrounding region.

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