

ULTIMA study to examine EkoSonic system for the treatment of PE

Company announces additional series of studies assessing EkoSonic system

EKOS has announced what is believed to be the first randomised clinical study designed to show the clinical benefit of an endovascular device to treat acute sub massive pulmonary embolism (PE) in comparison to anticoagulation therapy alone. The ULtrasound Accelerated Thrombolysis of PulMonAry Embolism (ULTIMA) clinical trial is currently in the final approval stages.

Current therapies for PE include aggressive anti-coagulation and in more extreme cases intravenous delivery of clot dissolving, thrombolytic agents. However, although anti-coagu-

lant therapy can reduce the mortality rate, they do not dissolve the embolism. In addition, thrombolytics actively dissolve emboli, but are associated with an increased risk of bleeding. Neither therapy completely dissolves emboli in all patients, leaving some patients with a chronic clot.

As a result, it is hoped that the ULTIMA randomised clinical trial will demonstrate that the EkoSonic system can dissolve thrombus and eradicate the need for anti-coagulant or thrombolytic therapy and their associated risks (See box for description of the EKOS system).

The multi-centre study will enroll 50 patients with PE and enlarged right hearts who will be randomised to receive either standard-of-care anticoagulation or the thrombolytic, Actilyse (Boehringer Ingelheim), delivered via the EkoSonic device. Importantly, the risks of using Actilyse thrombolysis via the EkoSonic system is reduced as the amount of drug necessary to dissolve a thrombus is decreased when using the EkoSonic system. This is because ultrasound increases the permeability of the clot while gently driving the drug into its interior. The investigators believe that by delivering Actilyse directly into the pulmonary embolism in the presence of the ultrasound generated by the EkoSonic device will result in prompt, complete dissolution of the obstructing embolism with restoration of right cardiac function and a reduction in the number of patients with long-term side effects from pulmonary emboli. ULTIMA enrollment is

expected to commence shortly and be completed by the first quarter of 2011.

"This study is, to our knowledge, the first randomised controlled trial designed to show the clinical benefit of an endovascular device to treat acute sub massive pulmonary embolism in comparison to anticoagulation therapy alone," said Principle Investigator, Dr Nils Kucher, University Hospital, Bern, Switzerland. "We intend to show that treatment with low-dose, ultrasound accelerated thrombolysis [EKOS] will rapidly improve right heart failure in these patients, without introducing the risks typically associated with systemic thrombolytic therapy."

Additional study sites include University Hospitals in Dresden, Munich and Greifswald, Germany, and several other sites.

DUET

The EKOS device is also undergoing assessment in the physician-sponsored DUET study. DUET is a Dutch multi-centre, randomised trial designed to compare ultrasound-accelerated catheter directed thrombolysis to standard catheter-directed thrombolysis in patients with recently thrombosed infrainguinal native arteries or bypass grafts. The study's hypothesis is that ultrasound-accelerated thrombolysis with the EKOS device will significantly reduce therapy time (by at least 12 hours) compared with standard thrombolysis alone without increasing the complication rate.

A total of 60 patients with recently (between one and seven weeks) thrombosed infrainguinal native arteries or bypass grafts with acute limb ischaemia Rutherford class I and IIa will be randomly allocated to either group A [standard thrombolysis] or group B [EKOS ultrasound-accelerated thrombolysis]. The anticipated duration of recruitment will be one year. The primary endpoint is the duration of catheter-directed thrombolysis needed for uninterrupted flow in the thrombosed infrainguinal native artery or bypass graft with outflow via at least one crural artery.

"Current therapy can take a significant amount of time (36-48 hours) during which the patient is restricted to a bed in a hospital monitoring unit, and bleeding complications increase with duration of thrombolysis," said Dr Jean-Paul de Vries, St Antonius Hospital Nieuwegein, The Netherlands. "This new ultrasound-accelerated technology promises to significantly reduce the treatment time. Such a reduction, if proven, could reduce treatment costs, patient discomfort, and the risk of bleeding, which is sometimes associated with these types of drugs."

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The technique

The EKOS MicroSonic Accelerated Thrombolysis (MSAT) is designed to provide faster, safer and more complete dissolution of thrombus. The device delivers ultrasound energy to a clot and causes fibrin strands to thin and loosen, exposing plasminogen receptor sites. Through ultrasound, thrombus permeability and thrombolytic penetration are dramatically increased and ultrasonic pressure waves force lytics deep into the clot and keep it there allowing the drugs to act faster, clearing clot sooner with reduced bleeding complications.

