

CLINICAL TRIAL ALERT

U.S. Clinical Trial Seeks Patients with Congenital Heart Valve Disease for Minimally-Invasive Pulmonic Valve Replacement

Children born with congenital heart valve disease typically face the burden of multiple open-heart surgeries throughout their lives, either to replace their “native” diseased valves or, as they age, their prosthetic replacement valves. This creates a number of challenges for them and their families, as they face repeated exposure to anesthesia and cardiopulmonary bypass, scar tissue that can result from multiple open-chest surgeries, increased risk for infection or illness and the disruption that the many surgeries and recovery periods can have on their lives.

A new alternative for people with a congenital defect in the valve between the heart’s right ventricle and the pulmonary artery is currently being explored. Transcatheter heart valve replacement, in which a prosthetic heart valve is delivered to the heart via a catheter, is making headlines around the world. According to a recent article in the *New York Times*, the new valves are the “next big thing in heart surgery” because they “make it possible to repair the heart without the rigors of chest-opening surgery.”

Patients are currently being sought for participation in a U.S. clinical trial that will assess the safety and effectiveness of a transcatheter heart valve replacement in patients with a failing pulmonary valve conduit.

This clinical study will enable doctors to offer a far less-traumatic treatment option, giving patients the opportunity to remove at least one open-chest surgery from their course of treatment, experience a quicker recovery and more easily resume their normal activities.

About the procedure:

- The valve – the Edwards SAPIEN transcatheter heart valve – is compressed to the approximate diameter of a pencil and threaded via a catheter through the circulatory system from a small incision in the leg. The valve is then deployed in the pulmonary valve conduit. This is accomplished as a "beating heart" procedure that does not require cardiopulmonary bypass or an open-chest incision, which facilitates a quicker recovery.

Additional information:

- Patients suffering from moderate to severe pulmonary regurgitation due to a congenital defect are encouraged to review the study criteria located here, and contact one of the clinical trial locations for additional information:
http://www.clinicaltrials.gov/ct2/show/NCT00676689?spons=%22Edwards+Lifesciences%22&spons_ex=Y&ank=4
- The study is known as COMPASSION: COngenital Multicenter Trial of Pulmonic Valve Regurgitation Studying the SAPIEN InterventIOnal THV

- Clinical Trial Locations:

Cedars-Sinai Medical Center
Los Angeles, California 90048
Principal Investigator: Rajendra Makkar, MD
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Rush Medical Center
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