

Medtronic starts trial of renal denervation system in Japan

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Singapore: Medtronic started Symplicity HTN-Japan, the first clinical trial with the Symplicity renal denervation system in Japan for patients with treatment-resistant hypertension. The clinical trial is an open-label study that will randomize subjects 1:1 to renal denervation vs. no denervation with both groups receiving maximal tolerated doses of anti-hypertensive medications. The clinical trial is being conducted in approximately 100 patients across 11 centers in Japan.

Treatment-resistant hypertension affects approximately 120 million people worldwide and is defined as persistently high blood pressure despite three or more anti-hypertensive medications of different types, including a diuretic. Research suggests that nearly one third of treated hypertensive individuals are considered resistant to treatment and these patients have a three-fold increase in risk of cardiovascular events compared to individuals with controlled high blood pressure.

"Persistent hypertension may increase the risk of stroke and cardiovascular events," said Dr Kazuyuki Shimada, former president of the Japanese Society of Hypertension, and principal investigator of the clinical trial. "This trial to confirm the efficacy of renal denervation in Japanese patients with the Medtronic renal denervation system may be the first step toward a positive future for patients with treatment-resistant hypertension, which can be difficult to treat with conventional blood pressure medications. If the results of the trial are positive, it may have a marked impact on the current strategies for treatment-resistant hypertension, for which effective approaches have not yet been established."

Renal denervation therapy is a minimally invasive, catheter-based procedure that modulates the output of nerves that lie within the renal artery wall and lead into and out of the kidneys. These nerves are part of the sympathetic nervous system, which affects the major organs that are responsible for regulating blood pressure: the brain, the heart, the kidneys and the blood vessels.

The Symplicity system's catheter and proprietary generator and algorithms were carefully developed through years of clinical experience to enhance the safety and effectiveness of the renal denervation procedure. The Symplicity renal denervation system has been used for five years to treat more than 5,000 patients with treatment-resistant hypertension worldwide. The

Symplicity renal denervation system was launched commercially in April 2010 and is currently available in parts of Europe, Asia, Africa, Australia and the Americas. The Symplicity renal denervation system is not approved by the US Food and Drug Administration (FDA) for commercial distribution in the US or Japan.

"The initiation of the Symplicity system clinical trial in Japan marks a pivotal milestone for the Symplicity clinical program and brings us one step closer to helping to address an unmet clinical need for people in Japan with treatment-resistant hypertension," said Mr Sean Salmon, senior vice president and president, Coronary & Renal Denervation, Medtronic. "With the initiation of this study, we continue our broad commitment to partner with the global medical community to explore the use of renal denervation in different patient populations."