

Study tests new therapy for treatment-resistant hypertension

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(Medical Xpress) -- Treatment-resistant hypertension affects nearly 6 million Americans and another 94 million people worldwide and is associated with increased cardiovascular risk, including stroke and heart attack, as well as heart failure and kidney disease. To help provide patients an effective alternative for effective disease management, the Vanderbilt Heart and Vascular Institute is participating in a clinical trial to test renal denervation, a new, minimally invasive catheter-based procedure for treatment-resistant hypertension.

Patients with treatment-resistant hypertension have [high blood pressure](#) that remains greater than 140/90 mmHg, despite treatment with three or more antihypertensive medications.

Renal denervation uses a tiny device threaded into the renal arteries to deactivate nerves to the kidneys. Once in place, the tip of the [catheter](#) delivers low-power, radio-frequency energy to modulate the surrounding [sympathetic nerves](#). When overactive, these nerves can raise blood pressure and contribute to heart, kidney and blood vessel damage.

"Renal denervation and ongoing treatment with antihypertensive medications have the potential to help patients achieve their target blood pressure levels," said Mark Robbins, M.D., assistant professor of Medicine and co-principal investigator of the trial with Jay Gainer, M.D., chief of the Vanderbilt Hypertension Center.

The clinical trial, known as SYMPLICITY HTN-3, is a randomized, controlled trial designed to evaluate the safety and effectiveness of the Symplicity Renal Denervation System and will enroll about 530 patients at more than 60 medical centers.

The Symplicity Renal Denervation System has been successfully used since 2007 to treat more than 2,000 patients worldwide and has been commercially available in Europe and Australia since 2010.

The system is not approved by the U.S. Food and Drug Administration (FDA) for commercial distribution in the United States.

"We've had multiple types of drugs around for the treatment of patients with refractory hypertension, but no significant improvement in care of these patients has been as effective as the results of initial Symplicity trials," Robbins said. "What we've seen is a marked improvement in blood pressure management."

"If the success of this procedure in the initial trials can be replicated in the United States, this therapy could be quite a breakthrough for a significant proportion of patients who chronically require four or more blood pressure medications to establish acceptable BP control," Gainer said.

More information: The trial is currently enrolling patients. Contact study coordinator [Sean Johnson](#) for more information.

Provided by Vanderbilt Medical Center

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