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Implantable device for sleep apnea studied

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For millions of Americans, trying to get a restful night's sleep is more like a nightmare.

The National Institutes of Health estimates one in 10 adults over 65 (a total of 18 million Americans) suffers from obstructive sleep apnea (OSA), a disorder in which obstruction in the upper airway can lead to interrupted breathing and sleep.

In OSA, the tongue and other tissues of the throat obstruct the airway during sleep, blocking breathing for sometimes up to a minute. These events can occur multiple times throughout the night and severe OSA has been linked with increased risks for cardiovascular disease, diabetes, stroke and accidents resulting from daytime drowsiness.

This spring, two UC researchers are collaborating in an international, multi-center trial on an investigational device for treatment of OSA.

The STAR (Stimulation Therapy for Apnea Reduction) trial will evaluate the safety and efficacy of the Inspire Upper Airway Stimulation (UAS) therapy in patients with moderate to severe OSA.

The UAS therapy, manufactured by Inspire Medical Systems, is an implantable device designed to prevent airway obstruction during sleep. The device, implanted near the clavicle, is connected to a stimulation lead positioned near the airway. There, the lead delivers timed, mild stimulation to the hypoglossal nerve on each breathing cycle.

"The idea is that, by stimulating the hypoglossal nerve, the device can restore tone to the muscles controlling the base of the tongue. This prevents the tongue from collapsing and obstructing the airway," says principal investigator David Steward, MD, UC professor of otolaryngology - head and neck surgery and director of the division of clinical trials within the otolaryngology department. "Regular stimulation of the tongue can result in a normal breathing pattern and, potentially, regular, uninterrupted sleep."

Current treatment options for OSA include CPAP (Continuous Positive Airway Pressure) therapy, weight loss, oral appliances or surgery. CPAP uses a nasal or full face mask that pushes air into the patient's airway. But many patients have trouble using the mask and don't adhere to the treatment.

"This could be a major breakthrough therapy for selected patients with sleep apnea who are truly intolerant to CPAP therapy," says co-investigator Victoria Surdulescu, MD, associate professor of medicine in the division of pulmonary, critical care and sleep medicine. "If this device is proven to be beneficial, patients will only have to carry a small remote control with them, making sleep more convenient wherever it needs to occur."

More information: The trial is currently seeking to enroll moderate to severe OSA patients who have not found success with CPAP. Unlike current surgical procedures for OSA, the UAS therapy does not require permanent alteration to a patient's airway. For more information about the STAR trial, call (888) 844-4811, or visit www.theSTARtrial.com or clinicaltrials.gov .

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