

New clinical trial examines a potential noninvasive solution for overactive bladders

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Keck Medicine of USC urologists are launching a clinical trial to evaluate the effectiveness of spinal cord stimulation in patients with an overactive bladder due to neurological conditions, such as a spinal cord injury or stroke, and idiopathic (unknown) causes.

Researchers will use a technique known as Transcutaneous Electrical Spinal Cord Neuromodulation (TESCoN), a noninvasive therapy that delivers low-intensity electric impulses to the <u>spinal cord</u>.

The trial follows a recent study published in *Frontiers in Systems Neuroscience* led by Evgeniy Kreydin, MD, a Keck Medicine urologist and assistant professor of clinical urology at the Keck School of Medicine of USC. Kreydin and colleagues treated 14 patients with <u>bladder</u> dysfunction due to either spinal cord injury, stroke, multiple sclerosis or idiopathic cause with spinal cord stimulation sessions three times a week for eight weeks. All patients reported improved bladder sensation as well as a reduced number of incontinence episodes and night-time bladder voiding.

An overactive bladder causes several urological problems, such as frequent urination and incontinence. Existing treatments for the condition can cause adverse side-effects or require invasive, highly specialized procedures.

"TESCoN is well-tolerated by patients and easy for doctors to administer," says Kreydin, who will be co-investigating the trial along with Keck Medicine urologist David Ginsberg, MD, a professor of clinical urology at the Keck School.

In this double-blinded, sham-controlled trial, half the participants will receive two one-hour sessions of TESCoN per week over 12 weeks. The stimulation will be applied via electrodes attached to a device that emits low-intensity impulses

through adhesive pads placed on the patient's back. The other half of the participants will receive a placebo, or sham stimulation over course of the trial.

The trial will track subjects' number of daily urination and incontinence episodes over 72-hour periods. Researchers will then compare the data between the beginning and the conclusion of the trial, and between those receiving the real or sham stimulation. In addition, trial participants will complete bladder symptom questionnaires before and after receiving the treatments to further track improvement.

TESCoN is developed by the medical device company spineX. Company founders will be initiating discussions with the U.S. Food and Drug Administration to gain regulatory approval for the procedure.

The exact mechanism of how TESCoN improves bladder function is not known. Kreydin speculates that the stimulation retrains the spinal neural networks to properly store and void urine and to regain bladder sensation. For patients with a spinal cord injury or a neurological disorder, the nerves controlling the <u>bladder</u> are either cut off or disrupted.

"The ultimate goal of the trial is to improve peoples' sense of well-being," says Kreydin. "An <u>overactive</u> <u>bladder</u> can cause discomfort, inconvenience and embarrassment. The more control patients have over their bladders, the more control they have over their lives."

More information: Evgeniy Kreydin et al, Transcutaneous Electrical Spinal Cord Neuromodulator (TESCoN) Improves Symptoms of Overactive Bladder, *Frontiers in Systems Neuroscience* (2020). DOI: 10.3389/fnsys.2020.00001



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