



**JOHN WAYNE
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Sponsor

Cala Health, Inc.

**Saint John's
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CLINICAL TRIAL ANNOUNCEMENT

PROSPECT: Prospective Study for Symptomatic Relief of Essential Tremor with Cala Therapy

The purpose of this study is to evaluate symptomatic hand tremor relief in the treated hand following stimulation with the Cala TWO device in adults with essential tremor over a 3-month duration

Essential tremor (ET) is one of the most common movement disorders in the United States, affecting up to 5% of the population. ET patients experience involuntary shaking of the hands, head and/or voice that can range from mildly limiting to severely disabling. Over time, tremor severity increases, affecting the person's ability to perform certain tasks or activities of daily living.

Treatment options are limited for those with ET. There are currently no medications specifically designed to treat ET, and medications that may be prescribed to relieve tremor symptoms are often limited by either inadequate efficacy or intolerable side effects. Tremor symptoms are poorly treated or refractory to first-line pharmacological treatment options in an estimated 25-55% of patients. A small subset of ET patients whose tremors are inadequately treated by medication choose to undergo deep brain stimulation (DBS), however it is a highly invasive procedure that carries significant risks.

The **Cala TWO** device offers patients with ET a novel non-pharmacological, non-invasive alternative, in the form of stimulation of peripheral nerves, to aid in hand tremor relief. This highly innovative form of therapy may have the potential for improving health and quality of life for ET patients.

Key Inclusion Criteria:

- Must be ≥ 22 years of age
- A diagnosis of essential tremor as confirmed from clinical history and examination by a movement disorder neurologist

Key Exclusion Criteria:

- Moderate to severe ethanol dependence
- Implanted electrical medical device, such as a pacemaker, defibrillator, or deep brain stimulator, or implanted metal in the wrist to be stimulated
- Suspected or diagnosed epilepsy or other seizure disorder
- Previous thalamotomy procedure and focused ultrasound for tremor treatment
- Peripheral neuropathy affecting the tested upper extremity
- Presence of any other neurodegenerative disease