# Study Utilizing the TremorStim TM Combination Device Therapy in Patients With Essential Tremor



ClinicalTrials.gov Identifier:
Recruitment Status Not yet recruiting
First Posted : December 12th, 2022
Last Update Posted : December 12th, 2022

**Sponsor:**
**TremorStim a Leonhardt Ventures LLC**

**Company Leonhardt Ventures LLC**
**Collaborators: TBD**

**Information provided by (Responsible Party):**
TremorStim a Leonhardt Ventures LLC Company

- **Study Details**

## Study Description

Brief Summary:

The study objective is to evaluate hand tremor relief in the treated hand following stimulation with the **TremorStim Combination Device Therapy** in adults with essential tremor, and healthcare resource utilization and total healthcare costs over a 12-month period.

| Condition or disease | Intervention/treatment | Phase |
|---|---|---|
| Essential Tremor | Devices: TremorStim Combination Device Package | Phase II |

**Detailed Description:**

This is a prospective, randomized, dual arm, pragmatic trial in a real-world setting to evaluate the effectiveness and health economics outcomes of the TremorStim Combination Device Package in reducing hand tremor and improving quality of life as measured by the Bain and Findley Activities of Daily Living (ADL) score relevant to the stimulated upper limb. Healthcare resources utilization and total all-cause healthcare will also be evaluated. The study will recruit approximately 300 patients: 150 in the intervention arm (TremorStim Combination Device Package) and 150 patients in the standard of care (SOC) arm. Subjects will be randomized to either the intervention arm or the standard of care arm (1:1).Subjects in the SOC arm will be asked to measure their tremor severity by doing daily postural holds with the TremorStim device package without actual stimulations. Subjects in the intervention arm will wear the device at home for a period of 12 months, during which they will deliver 40 min stimulation sessions, which can be started and stopped on demand. After the first month, the subjects who were randomized to the SOC arm will cross over to the intervention arm.

## Study Design

| | |
|---|---|
| Study Type : | Interventional (Clinical Trial) |
| Estimated Enrollment : | 300 participants |
| Allocation: | Randomized |

| | |
|---|---|
| Intervention Model: | Crossover Assignment |
| Masking: | None (Open Label) |
| Primary Purpose: | Treatment |
| Official Title: | Real World Evidence Study Utilizing the **TremorStim Combination Device Package** in Patients With Essential Tremor |
| Actual Study Start Date : | March 3rd, 2023 |
| Estimated Primary Completion Date : | January 2024 |
| Estimated Study Completion Date : | June 2024 |

**Resource links provided by the National Library of Medicine**

## Arms and Interventions

| Arm | Intervention/treatment |
|---|---|
| No Intervention: Standard of Care Arm<br>Baseline tremor power without stimulation (SOC arm) over the first month of the study. Subjects in the SOC arm will be asked to measure their tremor severity by doing daily postural holds with the **TremorStim Combination Device Package** without actual stimulation. | Standard |

| | |
|---|---|
| Experimental: Intervention with the **TremorStim Combination Device Package** arm<br>Tremor power after stimulation with **TremorStim Combination Device Package**. Subjects in the intervention arm will wear the wrist and head band devices together at home for a period of 12 months, during which they will deliver 2X daily 40 min stimulation sessions, which can be started and stopped on demand. They will be asked to wear the BodStim TM bioelectric stimulation body suit during exercise 40 minutes 2X a week. They will be asked to come to the investigational clinic once a month for 40 minute focused ultrasound treatment sessions will treatment time will be divided evenly between the head the the wrists of the patient, 20 minutes each alternating back and forth every 5 minutes. | TremorStimTM Combination Device Package<br><br>Device: **TremorStim TM wrist stimulation 40 minutes 2X a day**<br>Device: **TremorStim TM BrainBrand TM stimulation 40 minutes 2X a day**<br>Device: **BodStim TM** bioelectric exercise suit 40 minutes 2X a week with exercise<br>Device: **Ultrafocus TM** focused ultrasound treatment 40 minutes 1X a month in temples and wrists |

## Outcome Measures

**Primary Outcome Measures :**

1 Change in tremor power [ Time Frame: Month 1 ] Difference in tremor power after stimulation with **TremorStim Combination Device Package** (treated arm) and baseline tremor power without stimulation (SOC arm) over the first month of the study. Prior to and immediately after each of the first 40 stimulation

sessions and every 7th session thereafter, the TremorStim protocol will direct the patient to perform postural hold tremor tasks to measure tremor power pre and post stimulation. The SOC arm will perform a tremor measurement only, without any stimulation sessions, for 1 month.

**Secondary Outcome Measures :**

1 Bain & Findley Activities of Daily Living (ADL) scale subset score [ Time Frame: Month 1, 3, 6, 9 and 12 ] Bain & Findley ADL subset score relevant to the stimulated upper limb. The subset score is the sum of 8 rated tasks. Each task is rated 1 to 4, where a higher score indicates more severe tremor. Minimum subset score = 8; Maximum subset score = 32.

## Eligibility Criteria

### Information from the National Library of Medicine

*Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.*

| | |
|---|---|
| Ages Eligible for Study: | 22 Years and older (Adult, Older Adult) |
| Sexes Eligible for Study: | All |
| Accepts Healthy Volunteers: | No |

**Criteria**

**Inclusion Criteria:**

- Age ≥22years
- Aetna commercial fully insured OR Medicare Advantage population (inclusion of Medicare is contingent upon additional internal approvals)
- Two ICD claims for ET, at least seven days apart, in the last three years OR one ICD claim for ET followed by at least one dispensed pharmaceutical treatment for ET
- Contraindication to standard pharmacological therapy (Asthma, COPD, 1stor 2nddegree heart block) OR indicator of poor pharmacological acceptability as evidenced by drug switching behaviors OR indicator of drug resistance as evidenced by the use of third-line drug therapies including Clozapine, Mirtazapine, Gabapentin, Topiramate, Clonazepam or Alprazolam
- Willing and able to provide informed consent to participate in the study
- Willing and able to follow study protocol requirements
- Patients with PCP or neurologist provider encounter in past 18months

**Exclusion Criteria:**

- ICD-10 evidence of a pacemaker or defibrillator or a procedure code indicating pacemaker implantation, electrode renewal or calibration
- ICD-10 evidence of a deep brain stimulator or a procedure code indicating DBS implantation
- CPT/HCPCS evidence of thalamotomy, gamma-knife radio surgical thalamotomy
- NDC and CPT evidence of botulinum toxin the last 6 months as therapeutic injection in the upper limb
- Pregnant during the enrollment period
- Evidence of Parkinson's Disease
- Evidence of epilepsy
- Formal diagnosis of hypothyroidism and treatment
- Formal diagnosis of hyperthyroidism without evidence of treatment
- Formal diagnosis of dementia

- Evidence of Treatment with thyroid hormone supplements (2 Rx claims 28 or more days apart) or evidence of hyperthyroidism (2+ claims, 28 days or more apart)

## Contacts and Locations

*To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.*
*Please refer to this study by its ClinicalTrials.gov identifier (NCT number):*

### Locations

| **United States, California** |
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| **TremorStim** |
| Mission Viejo,<br>CA 92694 |

**Sponsors and Collaborators**
Leonhardt Ventures LLC