

# Study Protocol

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Official Title: Simultaneous Bilateral Radiofrequency Thalamotomy Targeting the Ventral Intermediate Nucleus for Medication-Refractory Essential Tremor

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Title: Simultaneous Bilateral Radiofrequency Thalamotomy Targeting the Ventral Intermediate Nucleus for Medication-Refractory Essential Tremor

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## 1. Background and Objective

Essential tremor (ET) is a common movement disorder that significantly affects daily function. This study investigates the safety and efficacy of simultaneous bilateral radiofrequency (RF) thalamotomy targeting the ventral intermediate nucleus (Vim) of the thalamus.

## 2. Study Design

Single-arm, open-label interventional study with 5 participants, conducted from April 2025 to September 2026 at Tokyo Women's Medical University.

## 3. Eligibility Criteria

Inclusion: Aged 20–70, ET diagnosis, medication-refractory, MMSE  $\geq 27$ , MRI-compatible, consented.

Exclusion: Bleeding tendency, MRI contraindications, intracranial lesions, pregnancy, or otherwise deemed inappropriate.

## 4. Intervention

Simultaneous bilateral RF thalamotomy under local anesthesia. Treatment starts on the dominant hand's contralateral side. Intraoperative MRI will confirm safety before proceeding to the second side. If complications arise, unilateral treatment only.

## 5. Evaluation Schedule

Pre- and post-operative assessments at baseline, 1, 3, and 6 months using CRST, QUEST, SARA, BDI, BAI, AES, MMSE, and MRI.

## 6. Outcomes

Primary: Change in CRST score from baseline to 6 months.

Secondary: Changes in QUEST, SARA, mood scales, MRI lesion evaluation, adverse events.

## 7. Statistical Analysis

Wilcoxon signed-rank test for pre-post CRST score comparison. Missing data will be excluded.

#### 8. Adverse Events

Expected: Intracranial hemorrhage <1%, dysarthria 10%, dysphagia 5%, numbness 5%, transient ataxia 5%.

#### 9. Ethics

IRB approval obtained. Written consent required. Compliance with the Declaration of Helsinki.

#### 10. Conflict of Interest

Managed under institutional COI policy.

#### 11. Publication and Data Sharing

Results to be published. Data sharing TBD.