

## A Pivotal Study Evaluating Safety and Efficacy of the ShiraTronics Migraine Therapy System in RELIEVing, Interrupting, and Preventing Chronic Migraine (RELIEV-CM2)

**Status:** Recruiting

### Eligibility Criteria

**Sex:** Male or Female

**Age Group:** 18 years and over

**Inclusion Criteria:**

- at least 22 years old - migraines started before 50 years old - migraines occurring for at least 12 months before starting the study - 15  
•26 headache days/month, among which  $\geq 8$  days has the features of probable migraine, and minimum of 2 headache-free days/month - use of preventive(s) migraine medication for at least 3 months before starting the study

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**Exclusion Criteria:**

- headache or migraine other than refractory chronic migraine (RCM) - previously implanted neurostimulator - received botulinumtoxinA (Botox) for any other medical or cosmetic reasons requiring injections in the head, face, or neck within the past 3 months - cervical radiofrequency ablation within 12 months - other implanted electrical stimulation device or any metallic implant located in the head including CSF shunt and surgical clip above the shoulder line (excluding dental implants) - women who are pregnant or breastfeeding or planning a pregnancy during participation in the study

### Conditions & Interventions

**Interventions:**

Device: Neurostimulator

**Conditions:**

Brain & Nervous System

**Keywords:**

Clinics and Surgery Center (CSC), chronic headache, Migraine Headache, Neurostimulator

### More Information

**Description:** This research study is testing a potential new treatment for refractory chronic migraine (RCM). The potential new treatment is called ShiraTronics Migraine Therapy. The purpose of this study is to demonstrate the safety and effectiveness of the ShiraTronics Migraine Therapy System. The ShiraTronics System delivers mild electrical pulses to nerves associated with migraine pain around the back and front of your head. These electrical pulses interrupt or change the transmission of pain signals to the brain, which can potentially relieve your chronic migraine pain and symptoms. The ShiraTronics System is approved by the United States Food and Drug Administration for investigational (under research) use, and not approved for sale.

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**Phase:** NA

**IRB Number:** STUDY00022988

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