Responsive Cortical Stimulation for the Treatment of Medically Intractable Partial Epilepsy


SUMMARY

• Treatment with the RNS® System resulted in a 41.5% reduction in disabling seizures by the end of the blinded period, compared to a 9.4% reduction in the Sham group.
• Stimulation was well tolerated with no mood or cognitive side effects.
• The rate of serious adverse events compared favorably to deep brain stimulation and intracranial monitoring.

METHODS

Study Design: Data from the 4 month blinded period of a prospective, randomized, controlled, double-blinded trial.

Population: 191 patients with medically refractory partial onset seizures

Effectiveness Outcomes: Change in seizure frequency rate in Treatment vs. Sham stimulation subjects

Safety Outcomes: Serious adverse event (SAE) rates

Other Outcomes: Mood and neuropsychological function

KEY RESULTS

Efficacy

By the end of the blinded period, patients in the Treatment group demonstrated a 41.5% reduction in disabling seizures compared to 9.4% in the Sham group.

Over the entire blinded evaluation period, the mean seizure frequency was significantly reduced \( (p=0.0122^2) \) in the Treatment group (-37.9%) compared to the Sham group (-17.3%).
Safety

Serious adverse event (SAE) rates with the RNS System compared favorably to:

- Deep brain stimulation for Parkinson’s disease
- Implantation of intracranial electrodes and epilepsy surgery

2.6% post-operative infection rate at implant site
2.1% post-operative hemorrhage rate

OTHER OUTCOMES

Mood (BDI-II, POMS, & CES-D)4

- No group declines in any mood inventory
- No difference in the number of Treatment and Sham patients experiencing an AE related to suicidality

Neuropsychological Outcomes5

- No group declines on any of 16 cognitive tests
- No difference between the Treatment and Sham groups in the frequency of cognitive AEs, including memory

Neuropsychological Outcomes5

There was no difference in seizure response for patients:

- Who had prior treatment with vagus nerve stimulation or a previous epilepsy surgery
- With mesial temporal compared to neocortical onset seizures
- With 1 or 2 seizure foci

Footnotes

1. 18 yrs. or older, refractory to 2 or more AEDs and with no more than 2 foci localized by diagnostic testing
2. GEE (Generalized Estimating Equation)
3. Not due to seizure-related head trauma
4. More detail in Meador, 2015 Epilepsy & Behavior
5. More detail in Loring, 2015 Epilepsia

See important prescribing and safety information in the RNS® System labeling. This is intended as supplementary information and should be used in conjunction with the labeling. Refer to the labeling for a description of the RNS® System and its components, indications for use, contraindications, warnings, cautions, adverse events and instructions for use. The manuals are available at www.NeuroPace.com.

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