

Responsive Cortical Stimulation for the Treatment of Medically Intractable Partial Epilepsy

MORRELL MJ, ET AL. NEUROLOGY. 2011 SEP 27;77(13):1295-304.

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 patients¹ 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

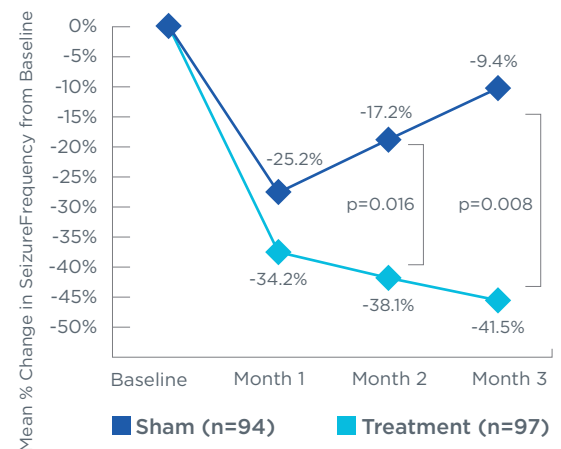
KEY RESULTS

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%).

Change in Seizure Frequency during Blinded Period (Treatment vs. Sham)





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 rate³

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

ADDITIONAL OBSERVATIONS

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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