Title: Evaluation of a Hand Held Nerve Stimulator (GammaCore VET™) for the treatment of refractory seizure activity associated with a diagnosis of canine epilepsy

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Study description:
Refractory idiopathic epilepsy in canine patients is a significant health problem in the veterinary population, occurring in at least 20% of epileptic dogs after attempted treatment with the most common and historically effective oral anticonvulsant medications (namely phenobarbital and/or potassium bromide). Therefore, approximately 20-30% of epileptic dogs require further treatment with drugs that have less documented efficacy.

Vagal nerve stimulation has been used in people for treatment of various diseases including epilepsy. Recently, a noninvasive method of vagal nerve stimulation has become possible with a handheld device which has been used in people for treatment of primary headaches and acute asthma. It is possible that, much like implanted vagal nerve stimulators, these new devices could have a widespread effect on the electrical and neurochemical environment resulting in seizure control, and will therefore allow a practical, cost-effective and accepted treatment for canine patients with poor seizure control. As part of a pilot study, we have treated 8 dogs with seizure disorders using this device and can confirm that there have been no side effects noted or safety concerns raised by the owners.

Inclusion criteria
- Dogs must be between one and six years of age at the first seizure.
- Dogs must have experienced no less than 4 seizures per month for the most recent 2 months
- Dogs must undergo a screening evaluation consisting of bloodwork (hematology and serum chemistry) and urinalysis; +/- thoracic and abdominal imaging if > 6yr old.
- Either:
  (1) Dogs must have a minimum six-month history of seizures with no abnormalities on neurological exam, or;
  (2) Dogs must undergo cerebrospinal fluid analysis, and advanced imaging to rule-out structural causes of seizures; clients will be responsible for funding these standard epilepsy investigations
- Dogs considered non-responsive to treatment will have been maintained on phenobarbital for 2 months and/or potassium bromide for at least 2 months and have no ‘successful’ improvement in seizure activity (defined as less than 50% decrease in seizures compared to initial status).
Exclusion criteria  
- Dogs with a systemic illness, specifically cardiac disease  
- Dogs with severe skin disease affecting the neck  
- Dogs needing emergency status seizure treatment requiring a change in his/her long term seizure treatment will be excluded or removed from the trial

Once enrolled, dogs will undergo a baseline assessment lasting 8 weeks (weeks 1 through 8) during which seizure frequency and severity will be documented. Once completed, dogs will return for a recheck visit during which he/she will be randomized to one of two treatment groups: a treatment group in which the device will be used on dogs for an eight week period and a group in which the device will not be used for another 8 week period.

Approximately 5 ml of blood will be collected at the week 0 and week 24 rechecks for labwork (CBC, chemistry profile, bile acid and Phenobarbital testing), in addition to urine for urinalysis. Dosage of preexisting anticonvulsant treatment will not be altered throughout the study. All owners will be asked to keep a daily diary regarding the use of the vagal nerve stimulator and any side effects that might be related to its use, as well as a diary that outlines seizure events.

Treatment with the vagal nerve stimulator consists of applying the device to the left side of the dog’s neck 3 times per day (i.e., in the morning, afternoon, and evening, with 8 hours separating treatments) for 90 seconds duration each treatment. At the end of the 8 week treatment period (weeks 9 through 16), dogs will return for a recheck and will be then treated with the device for an eight week period, regardless of his/her previous treatment assignment. A final recheck at Week 24 will complete enrollment.

Upon acceptance into the study, all recheck evaluations, initial and follow up lab-work (Day 0, Week 24) will be paid by the sponsor. The vagal nerve stimulators will be provided by the sponsor for use during study enrollment. The client is responsible for the cost of the initial examination and any diagnostics performed outside of study specifications.

Duration of study:  
This study is currently OPEN. Study participation is 24 weeks duration following enrollment.

Potential benefits to veterinary medicine:  
If effective, this study may provide a novel, noninvasive treatment for refractory idiopathic epilepsy with minimal side effects, which may ultimately provide a valuable option to veterinary practitioners for treatment of complicated epilepsy cases.