Clinical Research Project
Client Consent Form

Study Title: Intranasal midazolam versus intravenous midazolam for the management of canine status epilepticus: A multicentre randomized parallel-group clinical trial
Principal Investigator: Theresa E Pancotto
540.231.2430
tepdvm@vt.edu

One of the missions of the Virginia-Maryland College of Veterinary Medicine is to create, disseminate and apply medical knowledge through discovery, learning, and engagement. You are invited to participate in this mission by enrolling your animal in a clinical research study. Your participation is entirely voluntary, and you may withdraw your animal from the study at any time by notifying the Principal Investigator. There is no penalty if you choose not to participate.

Study Purpose:
To compare safety and efficacy of intranasal midazolam to intravenous midazolam for treatment of status epilepticus.

Study Design/Procedures:
Status epilepticus is a life-threatening complication of epilepsy. Benzodiazepines are gold standard treatment for status epilepticus in dogs and people. Various methods of delivery have been described: rectal, nasal, sublingual, intravenous. Standard of care is by intravenous administration in the hospital or rectal administration at home. Validating use of a medication via alternative route is necessary to provide recommendations for or against its use. Recently intranasal midazolam has been shown to have superior effects compared to rectal valium. Our goal is to compare intranasal midazolam to intravenous midazolam to establish better recommendations for treatment of status epilepticus, particularly in the home setting or when IV access cannot be obtained.

Risks and Benefits:
Both methods of administration of midazolam are known to be safe and efficacious. Intranasal administration may cause sneezing and slight irritation.

Study Costs and Compensation:
The study pays for the intranasal atomizer (MAD) device.

Confidentiality:
The data collected in the course of this study is confidential. In any publication or presentation of the study data, we will not include information that would make it possible to identify a research participant. Research records will be kept in a secure location; only researchers will have access to the records.

Statement of Consent:
In giving my consent by signing this form, I acknowledge that I have been informed of the purpose and nature of this study and its associated procedures, as well as any possible side effects.

I have read and understood the above information. I have been given the opportunity to ask questions and receive answers, and I consent to participate in the study. I further certify that I am the owner (or duly authorized agent of the owner) of ____________________.

(Animal’s name)

Owner or Agent Signature: ___________________________ Date: __________
Please don't hesitate to contact us if you have any questions or concerns about this study.
The research and procedures have been reviewed and approved by the Virginia Tech Institutional Animal Care and Use Committee and the Virginia-Maryland College of Veterinary Medicine Veterinary Teaching Hospital Board.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researchers, please contact:

Hospital Director,
Veterinary Teaching Hospital
Virginia-Maryland College of Veterinary Medicine
Address: 245 Duck Pond Dr., Blacksburg, Virginia 24061-0443
Phone: 540-231-4621

You will be given a copy of this form to keep for your records.