

Owner Informed Consent Form

Study Title for Study Participants: Amino Acid Concentrations in the Urine of Healthy Dogs

Official Title: Amino Acid Concentrations in the Urine of Healthy Dogs

What is a clinical trial?

Clinical trials are research studies that evaluate new types of treatment. Clinical trials may be designed to determine the effectiveness and side effects of new drugs or treatments, new surgical procedures, new diagnostic procedures, or novel approaches to treatment (such as gene therapy or immunotherapy). The UC Davis VMTH often has several clinical trials ongoing at the same time, so your pet may be eligible for more than one clinical trial. Your pet's veterinarian and the clinical trials team will discuss standard treatment and clinical trial options with you. It is your decision whether or not you want your pet to participate in a clinical trial. You may discuss your pet's participation with your family and your pet's veterinarian. If you have any questions, please ask your pet's veterinarian for additional information.

Why is this clinical trial being done?

The purpose of this study is to establish normal reference ranges for urinary amino acids in healthy dogs consuming dry, canned or commercial raw diets or home-prepared diets. Amino acids are the building blocks of protein. We are working with the Veterinary Laboratory Investigation and Response Network (Vet-LIRN) at the Food and Drug Administration to try to establish normal ranges for urinary amino acids in healthy dogs. The information from this study will be used as part of a larger investigation to understand the severity and duration of urinary amino acid loss for a small portion of dogs that develop Fanconi syndrome after consuming jerky pet treats. There will be about 150 pets taking part in this study.

What is the usual approach for establishing a normal reference range?

A normal reference range is established by collecting samples (in this case urine) from a large number of healthy dogs. We invite your dog to take part in this clinical trial because your pet is a healthy dog eating a dry or canned commercial diet, raw diet or home-prepared diet.

What are my other choices if my pet does not take part in this study or stops taking part in this study?

Participation in any clinical trial is voluntary. If you decide that you do not want your pet to participate in the study, your choice will not affect your pet's future medical care.

If I enroll my pet, can my pet stop taking part in this study?

Yes. You can decide to stop at any time and it will not affect the medical care of your pet. The study veterinarian will tell you about new information or changes in the study that may affect your pet's health or your willingness to have your pet participate in the study.

Please note that the study veterinarian can remove your pet from the study:

- If your pet's health changes, and the study is no longer in his/her best interest
- If new information becomes available
- If you do not follow the study protocols and rules

- If the study is stopped by the sponsor, UC Davis' Institutional Animal Care and Use Committee (IACUC) or a regulatory agency (e.g., FDA).

If you decide to remove your pet for any reason, it is important to let the study veterinarian know as soon as possible so that treatment can be discontinued safely. Additionally, please note that we will not remove any data that has already been collected from the trial database.

What are the study groups?

There is only one study group, healthy dogs consuming a commercial dry or canned dog food, raw or home-prepared diets.

What tests and procedures are required to determine if my pet can take part in this study?

Before your pet begins the study, you will need to complete the Feeding History Form asking about your pet and what they currently eat at home to find out if he/she qualifies to be in the study.

What tests and procedures will my pet have if my pet takes part in this study?

Your dog will not have to any tests or procedures. We simply need you to complete the questionnaire, collect a small amount of urine (a minimal amount of 15 ml or 1 tablespoon) in a clean cup we provide, and submit 2-3 photographs of the diet you are currently feeding your dog.

If the exams, tests, and procedures show that your pet can take part in the study, and you choose to enroll them, then the following will happen as part of the study:

We will ask you to complete the attached questionnaire about your dog and what your dog is currently eating at home. We will ask you to collect 15 ml or 1 tablespoon or more urine into the clean cup provided, and submit it to the clinicians involved in the study. In addition we ask that you take 2-3 photographs of your pet's current diet so we know exactly what he/she is eating.

Urine collected from your dog will be analyzed for amino acid content through the Amino Acid Laboratory at the University of California, Davis School of Veterinary Medicine. In addition, we will screen the urine for the presence of glucose, ketones, organic acids, and mucopolysaccharide through the PennGen Laboratory at the University of Pennsylvania, School of Veterinary Medicine. Results from the urine screen will be sent to the veterinarian who collected the urine sample for this study. While this study is being conducted in healthy dogs, it is possible in some cases that we may identify alterations in your dog's urine that indicate you should follow-up with your primary care veterinarian. If this is the case, and with your approval by signing this consent form, the results of your dog's urine sample will be sent to your primary care veterinarian. You will be notified to contact your veterinarian to discuss these findings.

This study does not cover any expenses related to follow-up appointments, diagnostics or treatments that are initiated because of any underlying medical issues found as part of this screening study.

How long will my pet be in this study?

Once you have complete the questionnaire, collected a urine sample and submitted photos of the diet, your dog has completed the study.

What possible benefits can I expect from my pet taking part in this study?

We cannot promise any benefits to your pet or other animals from your taking part in this clinical trial; however, possible benefits include contributing to the development of a reference range for urinary amino acids in canine urine that will be used as part of a larger study to understand the severity and duration of urinary amino acid loss for a small portion of dogs that develop Fanconi syndrome after consuming jerky pet treats.

What possible risks can I expect from my pet taking part in this study?

There are no risks to participating in this trial.

What happens if my pet experiences adverse event(s) because he/she took part in this study?

If your pet experiences adverse event(s) as a result of taking part in this study and is in need of medical treatment, please tell your study veterinarian. The study sponsors **WILL NOT** offer to pay for medical treatment for injury.

We do not anticipate the occurrence of any adverse events in dogs participating in this non-invasive study.

What are my responsibilities if my pet participates?

If you wish to have your pet participate in this study, you will be responsible for completing the questionnaire to the best of your ability, collecting a small urine sample (about 15 ml or 1 tablespoon), taking 2-3 photographs of your pet's food and submitting those to the study investigators. In some cases we may contact you to clarify your responses on the questionnaire.

What are the costs of my pet taking part in this study?

For more information about possible costs, please contact the investigator. The results of this study, including specimens collected, may have commercial value to the sponsors, the University of California Davis, and/or the researchers. You will have no legal or financial interest in any commercial development resulting from the research or from the information or materials collected.

There is no cost to you to participate in this trial.

What happens to the information collected for the clinical trial?

Your privacy is very important to us. Our researchers will make every effort to protect it. All client and animal details, and information obtained from the study will be considered confidential and will be used for research purposes. We will limit the use and/or disclosure of your information or that of your pet to people who have a need to review this information, including the study sponsor, the drug company or funding agency supporting the study and/or regulatory agencies (e.g., FDA). In addition to standard electronic medical records at the UCD VMTH, some of your pet's health information, and/or information about his/her specimen, from this study may be kept in a central database for research. Your name or contact information will not be put in the database. We may publish the results of this research but we will keep your name, the name of your pet, and other identifying information confidential.

We are working with Vet-LIRN at the Food and Drug Administration to try to establish normal ranges for urinary amino acids in healthy dogs. The information from this study will be used as part of a larger investigation to understand the severity and duration of urinary amino acid loss for a small portion of dogs that develop Fanconi syndrome after consuming jerky pet treats.

Who can answer questions about this study?

For specific questions about the study in which your pet is enrolled, concerns, complaints, or if you believe that the study has negatively affected your pet (e.g., an adverse event due to participating in the study), please contact the study veterinarian:

- ***Study Veterinarian(s): Drs. Andrea J. Fascetti and Jennifer A. Larsen***
- ***Contact Information:*** For questions or reporting of a trial-related adverse event, please contact.

Dr. Andrea J. Fascetti email: ajfascetti@ucdavis.edu

Dr. Jennifer A. Larsen email: jabones@ucdavis.edu

This research has been reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) and the Clinical Trials Review Board (CTRB). You may contact the IACUC office by phone at 530-752-2364 or by e-mail at iacuc-staff@ucdavis.edu if you cannot reach the investigator.

By signing below I agree to permit my pet _____ (insert name) to participate in this clinical study and undergo the procedures described to me above.

By signing below, I have read through this informed consent document and that a signed and dated copy of the consent form will be given to me.

Signature of Owner

Date

Printed Name of Owner

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent