Evaluation of a daily oral supplement to reduce or control clinical signs of environmental allergies

Purpose:

The purposes of this clinical trial are to 1) determine the efficacy of a daily oral supplement in reducing the severity of the clinical signs of moderate to severe canine atopic dermatitis - AD (environmental allergies) and, 2) examine the difference in the percentage of days when anti-itching supplementation is needed to control flares in your dog's allergies.

What qualifies my pet for this trial?

To participate in this clinical trial your dog must:

- Be at least 18 months of age at the start of the trial
- Body weight of at least 5 lbs or 2.27 kg
- Have history of non-seasonal or seasonally non-seasonal pruritus and AD (environmental allergies)
- Incomplete response to a minimum 8 weeks of a hydrolyzed diet or novel protein and carbohydrate exclusion diet (home cooked or commercial). Dogs should be stabilized on their diets for at least four weeks prior to enrollment in the study and this diet should be maintained throughout the trial.
- Probiotic -containing product (food, treat, or supplement) withdrawal 4 weeks prior to the start of the trial.
- Incomplete response to an approved flea control regimen for at least 8 weeks, and must continue this program throughout the trial.
- Dogs must be on an approved endoparasite control program, including heartworm for at least 8 weeks and must continue this program throughout the trial.
- No clinical signs suggestive of overt surface, superficial, or deep microbial skin infection (i.e., bacterial pyoderma and Malassezia dermatitis) at the time of entry. Dogs with bacterial and fungal disease are eligible for inclusion in the study only after resolution of their infections and withdrawal of oral antibiotics for 10 days.
- Allergen-specific immunotherapy is permitted if used for >12 months, the dose remains unchanged for 6 months, the clinical signs are stable, and the regimen is maintained during the trial.
- Essential fatty acid supplementation to diets is permitted if in use for >8 weeks, the clinical signs are stable, and the dosing regimen is maintained during the trial.
- Corticosteroid treatment withdrawal times are 2 weeks prior to the start of the trial for oral steroids (prednisone, prednisolone, dexamethasone, methylprednisolone, triamcinolone, prednisolone/trimeprazine) and topical ointments, sprays, lotions, shampoos that contain steroids, and 8 weeks for long-acting injectable steroids (Depomedrol®, Vetalog®). Cyclosporine and oclacitinib treatment withdrawal times are 2 weeks and 2 days, respectively prior to the start of the trial. Cytopoint™ withdrawal time is 4 weeks prior to the start of the trial.
- Miscellaneous compounds with known antipruritc activity including Staphage Lysate, gabapentin, monoamine oxidase inhibitors, pentoxifylline and tacrolimus withdrawal times are 1 week prior to the start of the trial. Any NSAID is to be discontinued 1 week prior to the start of the trial.
- Topical and oral antihistamines withdrawal times are 2 days prior to the start of the trial.
- Topical medicated wipes, mousses and shampoos withdrawal times are 5 days prior to the start of the trial.
- Off of oral antibiotics and antifungals for 10 days.

What does enrolling in this clinical trial involve?

Your dog will first be screened for eligibility to enroll in the clinical trial. Screening procedures include blood and urine sampling (free catch), as well as a fecal sample. Your dog must have a confirmed diagnosis of atopic dermatitis (environmental allergies). Next your dog's clinical signs will be graded using

an approved grading scale and you will mark a horizontal line on an itching scale at the level you believe your dog's itching falls at the screening appointment. If both the clinical sign and itching scores fall within the established enrollment criteria, your dog can be included in the clinical trial.

Each week you will be responsible for recording your dog's diet, treats, oral medication and topical treatments. You will also record the level of your dog's itch on a scale every Saturday until the trial ends. You will turn in the food, treat and medication logs at each visit as well as the itching scale.

At appointment visits on Days 60 and 120, blood samples will be obtained to monitor blood cell counts and organ function. Finally, at each visit you will be given a very brief survey as to how you perceive your dog's quality of life. The study is 120 days long.

Study procedures include a dermatology examination at the prescreening visit and the 5 study visits. The severity of the clinical skin lesions will be graded using a validated evaluation scale for canine environmental allergies. Routine hemogram and biochemical profile bloodwork will be performed at screening day 60 and day 120 (end of the study). A fecal analysis will be performed at the screening visit.

Client Compensation

All study visits (from screening to the 5 additional visits) and procedures costs associated with each visit are covered by the study.

Costs for medications and topical therapies needed to control itching flares are NOT included in this study and are the responsibility of the pet's caretaker/owner. Any treatments needed for adverse events attributed to the supplement or unrelated to the clinical trial shall be covered by the owner.

If the pet and client participate in all the scheduled study visits, the owners will receive a $100.00 credit on their Veterinary Medical Center (VMC) hospital account that can be used for hospital services, medications or food. The credit will expire after 1 year from the screening visit date.

Contact:

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If you believe your pet may be eligible to enter this study, please fill out a pre-screening questionnaire.