The HALT Study

Study Summary

This is a multi-site, blinded, randomized, placebo-controlled clinical field study to provide substantial evidence of effectiveness of a disease modifying drug intervention in the management of ventricular hypertrophy in cats with subclinical HCM. The study will be conducted at multiple clinical sites that are experienced in treating cats with HCM. The study will consist of up to a 14-day screening period, followed by a 12-month once-weekly dosing period, with five post-enrollment study visits.

Inclusion/Exclusion Criteria

A non-exhaustive list of the clinically relevant study inclusion and exclusion enrollment criteria are detailed below.

Pre Screening Inclusion Criteria

- Confirmed diagnosis of subclinical HCM or Abnormal NTproBNP result detected by a reference laboratory or in-clinic assay.

Inclusion Criteria

- Echocardiographic diagnosis of ACVIM Stage B1 or B2 HCM
- Male or surgically spayed female cat
- Body weight ≥2.5kg
- Age ≥18 months and <15 years at enrollment
- ACVIM Stage B2 cats should be receiving clopidogrel 18.75 mg prior to or from screening visit

Exclusion Criteria

- Cats with advanced or symptomatic HCM (ACVIM Stage C/D) at Screening or at any point in medical history
- Sexually intact female
- Cats unable to take and/or owners unable to administer oral medications
- Any echocardiographic diagnosis that is not associated with HCM
- Other significant systemic or congenital illness (e.g Diabetes Mellitus, IRIS stage 2 or greater CKD, hepatic disease, hyperthyroidism)
- Subjects requiring urgent treatment
- Active Infections
- Non-Healed Wounds
- Treatment with prohibited medications (e.g angiotensin receptor blockers, beta blockers, ace inhibitors, diuretics, calcium channel blockers, chronic use corticosteroids) and inability to undergo washout for at least 14 days prior to Screening.

Study Assessments

A summary of the study assessments to be conducted over the course of the HALT study is provided below.

Procedure	Screening Day -14 to -1	Day 0	Day 30 ± 10	Day 90 ± 15	Day 180 ± 20	Day 270 ± 20	Day 360 ± 30
Medical history (Inc. FeLV and FIV screen)	✓						
Systolic blood pressure	✓			✓	✓	✓	✓
Physical examination	✓		✓	✓	✓	✓	✓
Echocardiography	✓				✓		✓
3-min ECG	✓						
Thoracic radiographs	✓						
Clinical Pathology Sampling (blood and urine)	✓		✓	✓	✓	✓	✓
Cardiac Biomarkers	✓						✓

Study participation incentives

- Opportunity for your client to access a novel disease modifying treatment.
- Client access to board certified cardiologist care the duration of the study.
- Free of charge diagnostics required per the study protocol.
- Client compensation of $500 on completion of the study.

How to refer

- Visit HCMincats.com
- Select the investigation site(s) most local to you
- Select the veterinarian form
- Complete this form with details of the client/patient
- The investigator site will contact the owner as screening slots become available should the patient meet the inclusion criteria for the study. Study enrollment may be staggered at each investigation site.