

Investigation of a Traditional Chinese Medicine Herbal Therapy protocol for Treatment of Dogs with Stage II Splenic Hemangiosarcoma after Splenectomy

Clinical Study Criteria

Inclusion Criteria:

- Biopsy confirmed splenic hemangiosarcoma and no evidence of metastasis in dogs who have undergone splenectomy for ruptured splenic hemangiosarcoma within the previous 3 weeks.
- Client willing and able to bring patient to participating clinical trial center monthly for evaluation.
- Adequate organ function based on routine bloodwork (liver transaminase \leq 3x the upper limit of normal (ULN), creatinine \leq 1.5x ULN).

Exclusion Criteria:

- Any metastasis
- Concurrent medical problem with less than 1 year expected survival time
- Treatment with other supplements for cancer therapy including herbs, glandular, or homeopathic
- Treatment with chemotherapy

Study Pays For (\$1568 - \$2400 value per patient)

- All herbal medicine and supplement prescriptions in the HSA study protocol for up to 12 months of therapy
- Serum vitamin D, calcium, TK1 and CRP monitoring every 2 months during the enrollment period

Owner Responsibilities:

- Costs for:
 - Oncology Consultation and all office visits
 - CBC and Chemistry panel within 3 weeks of enrollment in the study
 - Thoracic radiographs within 3 weeks of enrollment in the study
 - Abdominal ultrasound within 3 weeks of enrollment in the study
 - Echocardiogram within 3 weeks of enrollment in the study for any patient with any of the following: significant arrhythmia not deemed to be solely related to splenectomy based on the judgement of the study clinician, pericardial effusion, changes on thoracic radiographs concerning for possible right atrial tumor, or clinical signs concerning for possible right atrial tumor.
 - Any other medications, medical treatments or testing needed during the study period as deemed necessary by the attending clinician
 - Thoracic radiographs and abdominal ultrasound every 2 months for restaging in order to qualify for full study benefits (dose escalation when metastasis is noted). (If restaging is not performed every 2 months, patient will not be eligible for dose escalation.)
- Bring patient to participating clinical center for re-evaluation by the study clinician once monthly
 - All Herbal medications and supplements must be brought to each recheck for weighing and refills
- Administration of all herbal medications and supplements for the entire duration of the study at the prescribed dosages
- Available for phone interviews related to the study, their pet's condition and survival
- Release of medical records from RDVM for study purposes

Exit Criteria:

- Dogs may be withdrawn from the study at any time, for any reason at owner's discretion
- Dogs may be withdrawn from the study at any time, due to non-compliance with the study protocol
- Dogs will be withdrawn from the study after completing 12 months of herbal therapy, death or euthanasia, whichever is sooner

Consent

I have read and understand the above information. I have been given the chance to ask questions and have had my questions answered.

I agree to comply with the owner responsibilities outlined above for the time in which my dog is enrolled in the study, up to a 12 month commitment.

owner/ guardian signature

date

witness signature

date