

Clinical Trial - Patient Disease: Canine Osteosarcoma

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Study Name: Canine Osteosarcoma Chemotherapy/Nutrition Study

Purpose of the study: The purpose of the study is to evaluate the effectiveness of treating Canine Osteosarcoma by one of the following three methodologies:

- Chemotherapy – CARBOPLATIN protocol
- Integrating Nutritional/Herbal Therapy in combination with Chemotherapy for Osteosarcoma (Nutritional protocol listed below)
- A Therapeutic Nutritional/Herbal Protocol for Osteosarcoma (Nutritional protocol listed below)

This study is designed to evaluate the treatment of Osteosarcoma with (1) Chemotherapy (2) Chemotherapy plus Nutraceutical/Chinese herbal therapy and (3) Nutritional/Herbal therapy alone.

Chemotherapy

Chemotherapy protocols are well documented in both the human and veterinary literature. The associated side effects of chemotherapy in people are well known. Stories relating to serious weakness, debilitation, uncontrolled vomiting and diarrhea and hair loss in people being treated with chemotherapy are quite common. The administration of chemotherapy for animals however, is not the same as for humans. Unlike human protocols, the decision to administer chemotherapy to animals takes into consideration the day-to-day quality of life and patient well-being. The chemotherapy protocols are selected to maximize the destruction of the cancer while minimizing any associated discomfort for the animal. As a result, most animals do not experience any of the untoward side effects and often feel an improved day-to-day quality of life.

Chemotherapy is used to treat both the primary cancer as well as the cancer cells that may have spread to other parts of the body. The action of most chemotherapeutics is to destroy to prevent the cells from duplicating and reproducing new cancer cells. In the destruction or prevention of abnormal cells, the goal is always to proceed with a minimal amount of side effects to normal cells and tissues.

Integrative Veterinary Therapy

Integrative Veterinary Medicine (IVM) also known as Complementary Veterinary Medicine (CAVM) combines natural and alternative approaches with conventional veterinary practice methods for the benefit of the patient. IVM utilizes complementary treatments such as Therapeutic Nutrition, Chinese Herbal Medicine and Homotoxicology along with a proper diagnosis relying upon internal medicine, ultrasound, radiology, blood evaluation and other recognized diagnostic techniques.

IVM has become quite popular as more and more people are seeking these therapies, especially for animals with chronic degenerative diseases. In people, it is estimated that above 50% of people utilize at least one form of IVM and visits to alternative practitioners far exceeds visits to conventional medical doctors. This trend is also becoming popular with animals as more and more veterinarians are offering alternative therapies such as acupuncture and homeopathy. This is particularly true when it comes to animals with cancer, which in dogs and cats is responsible for 50% and 40% of animal death in veterinary hospitals respectively. The major deterrent to more veterinarians offering complementary therapies is the lack of evidence or proof under accepted research methods and studies. This is the reason why in animals with cancer, complementary therapies are used primarily to support the animal and less as part of the therapy. Colorado State Veterinary School, one of the leading institutes in the use of complementary veterinary medicine states that no complementary therapies “have ever been documented to cure a cancer patient”.

It is for this reason they also state “Few can disagree that complementary medicine is becoming an important aspect of palliative and supportive cancer care, however there is not a single complementary intervention that has been demonstrated to constitute an effective cure for cancer. Therefore, it seems prudent to state that it is unethical to promote complementary medicine as a cancer cure in canine and feline medicine. False promotion of CAVM can mislead people into giving up effective conventional treatments; it can raise false hopes of caregivers; and it can financially exploit caring people who seek any help for their dog or cat”. Veterinarians and clients must seek out resources to define what is known about complementary therapeutics that have been used in the treatment of cancer and other diseases in animals and humans.

Caution needs to be employed when assessing the efficacy of complementary therapies. However, data that exist suggest that some of these modalities may be helpful in treating the canine and feline cancer patient. Well-controlled studies must be encouraged and performed, as they are essential to document efficacy and toxicity. The expanding post graduate opportunities for practicing veterinarians and the incorporation of didactic and clinical programs at key leading veterinary schools is an important step toward the logical use of complementary medicine in veterinary medicine”.

The purpose of this study is to evaluate the use of specific nutritional protocols for the treatment of cancer, both with and without chemotherapy and to establish evidence-based criteria for the use of therapeutic nutrition and herbs in the treatment of cancer in animals.

Criteria for Acceptance to the Study:

The animal must have been diagnosed with osteosarcoma, confirmed by biopsy, surgical amputation of the affected limb has been performed and the selection of any of the above protocols will be the first therapy that has been administered to the animal. For more information regarding entry criteria, please contact the study coordinator, Allyson Stewart, CVT at 203-838-6626. Initially the study will be conducted in the regional area of Rhode Island, Connecticut, New York and New Jersey. At the

discretion of Dr.'s Post and Goldstein it may be expanded to other geographical areas so long as the diagnostic evaluation and the Chemotherapy is performed by a Veterinary Oncologist and the criteria listed in this study (diagnosis, chemotherapy, nutritional therapy, blood evaluation etc) are followed and properly documented. For those animals entering category (3) Therapeutic Nutritional/Herbal Protocol alone, please contact 914-533-5162 for instructions.

PROTOCOLS

(1) Chemotherapy – CARBOPLATIN protocol

(2) Integrating Nutritional/Herbal Therapy in combination with Chemotherapy

a. Chemotherapy - CARBOPLATIN protocol

b. Integrative therapy protocol

- Immune/Cancer Formula - 1 tablet for each 25 lbs of body weight BID
- Bone Support formula - 1 tablet for each 25 lbs of body weight BID
- Maitake DMG extract – 2 drops for each 10 lbs of body weight BID
- Herbal Osteosarcoma Formula – 1 capsule for each 10 lbs of body weight BID or TID
- Homotox Combination – Bone + Lymphatic + Echinacea + Inflammation

Note: A complete blood evaluation will be performed on all animals in this category and based upon the results and associated medical issues or organ disease, a custom blended nutrient powder may be recommended in place of the Immune Cancer Support Formula. Doses will vary based upon the animal's condition.

(3) Therapeutic Nutritional/Herbal Protocol

- Nutraceutical Powder (Custom Blended for the Individual Animal based upon a Nutritional Blood Test (NBT) results).
- Maitake DMG extract) – 1 ml/25 lbs body weight BID
- Herbal Osteosarcoma Formula – 1 capsule for each 10 lbs of body weight BID or TID
- Homotox Combination – Bone + Lymphatic + Echinacea + Inflammation

Diet

In all three treatment categories, the diet will be consistent and the animal caregiver will follow the dietary recommendations as listed below.

- Flax seed oil (No fish oil allowed)
- Protein – Beef, Pork, Venison, Buffalo or Tofu
- No Chicken, Turkey, Lamb, Eggs

Commercial choices

Some Dry Choices:

- Natural Balance Vegetarian
- Dr Harvey's dry premix
- Wysong Vegan (Dry)
- Pet Guard organic vegetarian

Some Canned Choices:

- Evangers 100% Beef
- Natural Balance Canned beef
- Wysong canned beef
- Evo 95% Beef
- Evo 95% Venison
- Blue Buffalo Canned Beef Dinner

Guidelines for Home Cooking

- 50-75% meat protein
- 20% complex carbohydrates
- 20% fat (rich in omega 3 and 6 – no chicken or fish oil)

Sample Home prepared diet

- 1 lb. Organic or free-range beef or pork (Tofu OK)
- 1 ½ cup Dr Harvey's or Organic brown rice
- 2 Tbs organic yogurt
- 1 Tbs Organic flaxseed oil
- ½ cup organic carrots
- 1 Tbs chopped organic parsley
- 2 cloves organic garlic

Clients Responsibilities:

This study requires visits to the Veterinary Oncology and Hematology Center in Norwalk for all diagnostic and blood evaluation irrespective of which category of therapy is selected. The client is responsible to must schedule all appointments as directed by the attending veterinarian.

Financial Parameters of the Study:

The client is responsible for:

- The diagnosis and surgical treatment of the disease.
- Once accepted into the study the following will be paid for by the client (estimated for a 70 pound dog). Costs will vary based upon weight and severity of illness.
- Examination – Oncology Consultation - \$140
- Recheck evaluation \$75
- Blood evaluation (Nutritional Blood Test)- \$170
- Blood evaluation – CBC - \$56
- Chemotherapy protocol – Approximately \$4000-7000
- Nutritional Consultation - \$175
- Nutritional Blood test evaluation (Non-Chemo category) - \$300
- Nutraceutical/Herbal therapy - \$75-250 per month