

# Cell Therapy for Metastatic Osteosarcoma

## VCT24005853

### Study Summary Listing:

**Scientific Title:** CAR iNKT cells for Metastatic Osteosarcoma

**Public Title:** Cell Therapy for Metastatic Osteosarcoma

**Name of Condition Being Studied:** Metastatic Osteosarcoma

**Description:** In this study we will investigate the therapeutic potential of a type of white blood cell known as invariant natural killer T (iNKT) cells that are made from the blood of a healthy donor dog. iNKT cells are potent immune cells that kill cancer cells in mouse models and in some human cancer patients. In this study, we will use iNKT cells that express a cancer targeting receptor known as a chimeric antigen receptor (CAR). The CAR directs the modified iNKT cells to the cancer cells which are then killed. The CAR-iNKT cells also will further activate the patient's own immune system to help kill the cancer cells. The purpose of this study is to determine the safety of CAR-iNKT cells, their maximum tolerated dose, how long they will remain in the patient and their effectiveness against bone cancer that has spread to the lungs.

**Species:** Canine

**Recruitment Status:** Recruiting

**Recruitment Dates:** 2024-11-23 - 2025-06-01

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**Inclusion Criteria:** Dogs with a histopathological diagnosis of B7-H3+ appendicular osteosarcoma (the expression of the target protein B7H3, will be determined by the study team, who will perform immunohistochemistry on a portion of the archived tumor taken from the initial site in the leg either pre-amputation or at the time of amputation), dogs who have undergone standard of care amputation followed by 4 to 6 doses of carboplatin, dogs who have not received cytotoxic chemotherapy for at least 8 weeks, dogs with evidence of pulmonary metastatic disease, adequate hematologic parameters, and hepatic and renal function, no significant co-morbidities, expected survival time of at least 2 months at the time of enrollment, body weight of at least 18kg.

**Exclusion Criteria:** Dogs without evidence of B7-H3 expression on primary appendicular osteosarcoma as determined by IHC, dogs receiving cytotoxic chemotherapy or who have received cytotoxic chemotherapy within the last 8 weeks, clinically significant abnormalities on baseline complete blood count and/or biochemical profile, significant concurrent illness (including autoimmune or immune mediated disease or history of autoimmune or immune mediated disease, significant proteinuria, infectious disease etc., any unregulated chronic disease for which the dog is receiving daily medication. This includes but is not limited to: hyperadrenocorticism, neurologic disease, heart disease, liver disease, and/or renal disease.

**Potential Medical Benefits:** The overall goal is to see either stable disease or regression of established pulmonary metastatic osteosarcoma lesions.

**Potential Medical Risks:** <p>Possible side effects include cytokine release syndrome (high fever, lethargy, inappetence,&nbsp;low blood pressure,&nbsp;fast heart rate, nausea, vomiting), Graft versus Host Disease (GVHD) (CAR-iNKT cells could attack patient's own tissues causing skin ulcerations, gastrointestinal symptoms, vomiting, and/or diarrhea), in target, off tumor cytotoxicity (damage to tissues in the body other than the cancer cells), dyspnea and tachypnea (difficulty breathing, rapid breathing), bone marrow suppression (increased susceptibility to infection), lethargy, fever, anorexia, nausea and vomiting, allergic reactions during cell infusion (facial and tongue edema, pruritis, vomiting, diarrhea).&nbsp;</p><p><br></p>

**Financial Incentives:** Fully funded including initial screening

**Type of Funding Source:** Government

**Name of Funding Source:** NIH/National Cancer Institute

## Study Protocol Details:

**Study Type:** Interventional

**Investigators 'Masked'?:** Yes

**Owners 'Masked'?:** Yes

**Intervention Type:** Biologic/Vaccine

**Intervention Name:** <p>A single dose of genetically modified CAR-iNKT cells (donated by a healthy donor dog), administered intravenously after a single, low dose of pre-conditioning chemotherapy. Dogs will be monitored for responses to therapy using blood work and thoracic radiographs. </p>

**Control Group Intervention:** No control group

**Primary Outcome Event:** Safety, tolerability and determination of maximum tolerated dose of CAR-iNKT cells

**Primary Outcome Measure:** Serial blood work assessment, bone marrow aspirate and serial thoracic radiographs

**Primary Outcome Endpoint:** <p>Safety, tolerability and identification of maximum tolerated dose of B7-H3 CAR-iNKT cells, persistence of allogeneic (cells from a healthy donor dog) CAR-iNKT cells in vivo, therapeutic effect on metastatic osteosarcoma.</p><p><br></p>

## Study Contact Information:

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## Study Location:

**Primary Study Location:** University of Pennsylvania Ryan Hospital