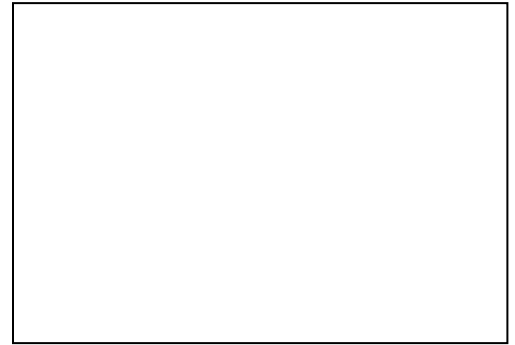


CLIENT CONSENT

Harnessing Mesenchymal Stem Cell Antimicrobial Activity: Preclinical Evaluation in Dogs with Antibiotic-Resistant Infections



**James L. Voss Veterinary Teaching Hospital
Colorado State University**

Overview

Chronic infections with antibiotic resistant bacteria are a problem of increasing magnitude in both veterinary and human patients resulting in serious health complications and increased cost of health care.

Previous laboratory studies have shown that mesenchymal stem cells (derived from adipose tissue) have antimicrobial activity against chronic wound infections in other species and have activity against multiple drug resistant bacteria in culture. These cells have been safely administered to dogs with other medical conditions.

This study is intended to evaluate the efficacy of stem cell therapy in chronic wound infections in dogs with resistant bacteria that have failed conventional therapy.

Study Details

We are recruiting dogs that have an infection (soft tissue, bone or implant infection) that has not responded to appropriate therapy for a period of at least 30 days. For your first visit, your dog will be screened for eligibility with a physical exam and review of the culture results and treatment and possibly radiographs and/or labwork. The first stem cell injection will be scheduled at that time. There will be 3 stem cell injections 2 weeks apart with a

follow up visit 2 weeks after the last injection. There will be two small biopsies taken of the area at the time of the first injection and at the follow up visit. For the biopsies your dog will be given a mild sedative and pain medication and local anesthesia will be used around the biopsy area. At the time of each injection and at the follow up visit a small needle will be used to collect samples for culture of the wound site. Your dog will remain on antibiotics for the duration of the treatment.

Is There Any Harm To My Pet?

Although this exact procedure has not been performed in dogs with chronic wound infections, mesenchymal stem cells have been given to dogs for other conditions, and we have administered adipose-derived stem cells to many cats with chronic kidney disease. Possible complications associated with receiving a tissue product from another animal include anaphylaxis, fever, and thromboembolic events. However, allogeneic (transfer between individuals) stem cell therapy is currently being performed in many species, including humans, with no obvious sign of the body rejecting the stem cells. Finally, as with any biopsy or fine needle aspiration of a wound, there is a minimal risk of bleeding and infection, and with any sedative there is a risk of mild to severe reaction. Your dog's doctor will choose sedatives safe for each individual patient, and your dog will be closely monitored during and after sedation and biopsy to minimize any risks.

Whom Should I Contact with Questions?

If there are any questions regarding the study protocol I may at any time request to speak with Dr. Valerie Johnson (valerie.johnson@colostate.edu, 970-297-5000). **What Are The**

Benefits For Me and My Dog?

Your dog will receive a novel therapy for an otherwise often fatal disease, and the cost of preparing and administering the

stem cells will be borne by the study. While we cannot predict the clinical benefit to your dog, in experimental models of wound infections have shown considerable benefit with this treatment. You and your dog will also be helping to advance the study of this important new therapeutic option.

It is important to know that the study is unable to cover the costs of additional treatment or complications associated with the primary wound infection.

Consent

I, the undersigned, am the owner or authorized agent for the owner, and agree to enter my dog into the clinical trial “Harnessing Mesenchymal Stem Cell Antimicrobial Activity: Preclinical Evaluation in Dogs with Antibiotic-Resistant Infections. The study design, objectives and procedures of the study have been clearly explained to me. I understand the risks of the procedures being conducted as part of this study. I give my permission to publish data generated from this study for the benefit of the scientific community. I understand that my pet will not be identified individually in any scientific publication or presentation resulting from this study. Following the discussion of the study protocol and after reading the above material, I voluntarily consent to enter my pet into this clinical trial. I agree to participate in this clinical study and will follow the instructions of the veterinarians as it applies to the protocol.

_____ Date: _____
Signature of owner/agent

_____ Date: _____
Witness