



“Efficacy of equine allogenic bone marrow derived mesenchymal stem cells for treatment of lameness and musculoskeletal injuries in horses”

Purpose and Brief Explanation: You are invited to participate in a clinical trial involving the use of bone marrow-derived equine stem cells to treat musculoskeletal injuries in horses. Recent studies in horses have shown promising results using adult stem cells to treat equine osteoarthritis, muscular damage, traumatic wounds, and tendon/ligament injury. Current research appears to demonstrate that horses treated with MSC therapy have shown substantial improvements in clinical signs and case outcomes.

The KSU Veterinary Health Center is participating in a clinical trial using allogenic bone marrow-derived mesenchymal stem cells under an Investigational New Animal Drug Application (INAD). The University of Tennessee Knoxville holds the Investigational New Animal Drug registration with the FDA to produce these cells in a GLP certified laboratory. These allogenic cells have been characterized *in vitro* and results published in two papers (Carter-Arnold et al. 2013 Equine Vet Journal & Ursini et al. 2019 Equine Vet Journal). These papers demonstrate donor selection criteria to serve as a source of allogenic MSCs and, most importantly, that the therapeutic use of the selected cells is safe and does not lead to known adverse effects in recipient horses. **The cells described above are considered Investigational products and any practitioner using these in client – owned animals are the Research Investigators**

The cells utilized by the KSU VHC (from the UT VMC) are derived from bone marrow, which was harvested from a selected donor horse, grown in culture, and cryopreserved. The cells will be shipped overnight in a cooled, self-contained shipping container. KSU VHC clinicians will administer the cultured cells into the injured area on the same day the cells are received. VHC clinicians will provide regular, follow up examinations at the VHC to evaluate healing and efficacy of the therapy. Any adverse reactions must be reported to VHC clinicians who will then notify the University of Tennessee and the FDA as a requirement of any INAD study. Owners will refer to their discharge summaries regarding any additional instructions for follow-up care or study related recommendations.

Eligibility: Horses with musculoskeletal injury. Horses must be examined, diagnosed and receive an appropriate treatment recommendation by a KSU VHC clinician.

Fees for Services: All costs associated with physical examination, blood work, diagnostic imaging, hospitalization, treatment administration and follow-up visits to the VHC will be the responsibility of the owner. Patients treated with the stem cell therapy will NOT be charged for stem cell processing and isolation or for the cells themselves.

Owner Responsibilities: Owners agree to report any adverse events to the VHC clinicians in a timely manner and to return for rechecks as prescribed by VHC clinicians. In the event that a survey is conducted as part of this study, owners agree to complete the survey.

Contact for more Information: Kris Richardson, Clinical Trials Coordinator at the Veterinary Health Center. Email: ClinicalTrials@vet.k-state.edu Phone: (785)-532-3046