UTCVM LARGE ANIMAL SERVICES

CLINICAL TRIAL

Effect of Intra-Articular Allogeneic Mesenchymal Stem Cell Injections on Osteochondral Activity in Osteoarthritic Joints

Purpose of study

Bone marrow-derived mesenchymal stem cells (BM-MSCs) have demonstrated broad potential for use in regenerative therapies for osteoarthritis (OA) treatment in human and equine patients. Allogeneic BM-MSCs (MSCs from a donor) possess certain advantages for therapeutic use over autologous MSCs (MSCs harvested from the same individual) such as readiness for injection with reduced culturing and processing time and consistency of a high-quality product. The goal of this study is to determine the response of bone and cartilage to two allogeneic BM-MSC intra-articular (into the joint) injections within osteoarthritic joints of horses.

Horses with previous diagnoses of osteoarthritis will be utilized. After initial evaluation, a new set of xrays will be collected. The horse will undergo a physical exam and lameness evaluation (within the limits of the horse's ability and comfort). The horse will receive two stem cell (allogeneic BM-MSCs) injections into one osteoarthritic joint: one injection on day 1 and an additional injection 3 weeks later (day 21). Joint fluid will be collected just prior to stem cell injections through the same needle that stem cells are injected (routine for many joint injections). Joint fluid will be collected at two additional times: 7 days following each injection (day 8 and day 28). All joint injections and fluid collections will be performed with the horse sedated. Sterile preparation will be performed prior to any injections. The horse will receive an additional physical exam and lameness evaluation around 3 months and 6 months after the initial BM-MSC injection. The horse will be stalled for observation overnight for one night following each joint fluid collection, and for two nights following each BM-MSC injection. Horses can be brought to the clinic. Alternatively, joint fluid collection/injections may possibly be able to be performed on the farm as long as horses are with a one hour drive of UTK CVM.

Enrollment criteria

Animals enrolled in this study should be healthy and free of any obvious clinical infectious disease. Please inform the study contact if your animal has not received vaccinations as required by your veterinarian. Horses should have received a diagnosis of osteoarthritis previously. Only joints where joint fluid can be collected will be utilized (pastern joints and lower hock joints are unlikely to be included). Horses may remain on any medications through the entirety of the study that they are on at the start of the study. Medications should not be changed unless the condition/health of the horse requires it. Any new supplements or medications or supplement/medication changes should be disclosed to the investigators.

The participation in this study is voluntary and withdrawal from the study is permitted at any time requested without any repercussions.

Information from this study may be used in a published media and/or used for educational purposes but the status of disease in the animal, name of client/owner, and animal name will remain confidential.

Study procedure

The total duration of the study for each horse is six months. The initial study period involving injections and joint fluid collection is 1 month. Horses will be examined, joint fluid collection will be performed, and two BM-MSC injections will be performed. Then, the horse will be reexamined three months and 6 months after the initial BM-MSC injection.

Risks associated with this study include joint sepsis as a result of repeated joint injection/fluid collection, which is a very low risk. All joint fluid collection and injections will be performed sterilely. Joint injections are regularly routinely performed in horses. Another risk is a joint "flare." Stem cell injections can stimulate the joint, resulting in increased joint fluid and local inflammation (slight swelling around the joint). This is known to be greater after the second injection. This stimulation is thought to be necessary to encourage the body to heal, but it can make the horse sore for a short time (typically 24-72 hours) following stem cell injections. If the horse is already on an NSAID (bute or Equioxx), this can help minimize this response. If the horse is not on an NSAID and a flare does occur, bute administration for 3-5 days may be recommended. Allogeneic stem cells from UTK are routinely provided to veterinarians around the country to treat joints, tendons, and ligaments (see additional stem cell form).

Study benefits

There is no cost or cash compensation associated with participation in this study. Allogeneic stem cells from UTK cost $1080 for the first injection and $900 for the second injection (not including shipping if necessary). This is the cost of the cells alone, and does not include the cost of sedation, sterile joint preparation, or injection. The x-rays normally cost around $200 (not including additional visit fees). Lameness evaluations typically cost around $200 (not including additional visit fees). Overall, enrollment in the study will provide a value of around $3000-3500 at no cost to owners.

Contact information

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