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AMC stem cell study to investigate intra-arterial injection for kidney disease

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By: Daniel R. Verdon
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NEW YORK, N.Y. — A novel new study at the Animal Medical Center (AMC) is investigating the impact of intra-arterial injection of stem cells on chronic kidney disease in cats and protein-losing nephropathy in dogs.

The feline study has been fully funded, and the veterinary research team of Drs. Allyson Berent, Chick Weisse, Cathy Langston and Pam Schwartz ultimately will enroll 30 cats with IRIS stage 3 chronic kidney disease in the randomized placebo controlled study. The team plans to conduct a separate study in dogs with protein-losing nephropathy (glomerulonephritis).

The research team's goal is to come up with novel treatments to stop the progression of kidney disease. Thirty-five percent of cats over the age of 13 suffer from chronic kidney disease, and it's considered an epidemic in feline medicine, Berent says.

Many of the current approaches to chronic kidney disease focus on managing the symptoms of the disease.

"We put them on a phosphate binder because they are hyperphosphatemic or put them on subcutaneous fluids to make their creatinine levels better because they are chronically dehydrated, none of those things are treating the kidney; they are treating the uremia and the symptoms. We are looking at trying to treat the kidney directly."

The study's population will focus on cats with IRIS stage 3 chronic kidney disease with creatinine levels between 2.9 and 5. This population of cats has a one to three-year life expectancy. "We thought that was a better group to select since they will likely decline from the chronic kidney disease."

The approach, intra-arterial injection, shows promise too, Berent says, since it will help target the diseased organ. In chemotherapy, the target tumor will get eight to 20 times the dose by using this delivery method and it seems in research models the same is true for stem cells.

"In all of the studies that looked at delivery, it's been shown that intra-arterial delivery may be better than intravenous delivery. But it has never been studied like this in clinical patients, particularly cats or dogs."

The stem cells, Berent explains, will be harvested from adipose tissue. "There are a lot of other things in the fat, not just stem cells, that help decrease inflammation, decrease fibrosis, improve the environment of the disease organs. The study seeks

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to determine if the treatment improves kidney health. If it does, why? Is it the stem cell or the environment that the fat is creating in the kidney that make (the organ) healthier. That is not something we know. And a lot of people are doing research to figure that out. What we do know is that in rats, sheep and mice, the environment created is much healthier and kidney function is improved. Most of that is not a regenerative effect; it is a paracrine effect, meaning it changes bad cytokines to good cytokines. It decreases cytokines that cause fibrosis. It decreases cytokines that cause more inflammation and vasodilation and vasoconstriction in appropriate and inappropriate areas. It is creating an environment of a healthy tissue and stops that cycle of interstitial fibrosis and nephritis," Berent says.

Over the next three years, the AMC research team will study these cats and dogs. The funding for the cat study covers \$14,000 worth of care that includes stem cell harvesting, stem cell delivery and all the follow-up care over the entire three years.

To date, the research team enrolled their second patient. Six cats will be in the pilot study to prove safety, and the rest of the animals will be enrolled in the future phase II looking at long-term efficacy. Phase II is randomized-blinded and placebo controlled.

The canine study will look at protein-losing nephropathy (glomerulonephritis). While this study has not yet been funded, AMC veterinarians have performed intra-arterial injection of stem cells on 12 dogs with various forms of CKD or AKI and have proven the procedure is safe, Berent says. Those dogs have been in various stages of chronic kidney disease, whether it is glomerulonephritis, renal dysplasia, glomerulosclerosis, renal fibrosis or acute kidney injury from toxicity. All but one of the dogs is still living.

"We have been pleased so far, and it seems like the earlier the stage of CKD we get to them, the better they do. A lot of these cases we would have expected them to be dead within 30 days, and they are alive and well over a year. Whether it is the stem cells or just luck, it is not clear, but hopefully these studies will determine that."

If you are interested in enrolling patients in the study, call Berent at (212) 329-8763.

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