

**Retroperitoneal Allogeneic Adipose-derived Mesenchymal Stem Cell Injection for
Treatment of Chronic Kidney Disease in Cats**

Client Consent Form

**Colorado State University Veterinary Teaching Hospital
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Client ID



Client Information – What is the study about?

Chronic kidney disease is a common disease in older cats. This is typically a progressive disease for which there is no definitive treatment. Currently, other than kidney transplantation, only supportive care home treatments are available to try and slow the progression of the disease. Recent studies have shown that stem cell therapy has the potential to improve kidney function in rodents with kidney failure. Proposed benefits of stem cell therapy include improvement of kidney values, promotion of cellular regeneration and healing, prevention of fibrosis and improvement of proteinuria.

We have previously performed a pilot study in cats where stem cells were injected intravenously. In this study no cat suffered any ill effect from the treatment and a few cats had mildly improved creatinine and Glomerular Filtration Rate (a measure of kidney function). The purpose of this study is to further explore stem cell therapy for chronic kidney disease in cats by injecting them into the area around the kidney.

Is your cat eligible to participate?

Cats that have been diagnosed with chronic stable kidney disease (creatinine 2.0 to 5.0 mg/dL), without evidence of hereditary kidney disease, based on bloodwork and ultrasound evaluation, are eligible for entry into the study. Eligible cats must have a current labwork panel (CBC, chemistry, urinalysis, urine culture, thyroid level, and blood pressure) and evaluation of the kidneys by ultrasound. If a heart murmur is present, cardiac ultrasound (echocardiogram) is required to rule out significant heart disease. Concurrent diseases such as diabetes, hyperthyroidism, cancer or heart disease would also be reasons for exclusion from the study.

Other concurrent therapies such as kidney diets, famotidine, potassium supplementation, ACE inhibitors and anti-hypertensives are allowed, but no changes in therapy can be made during the study time period. Based on the severity of your cat's disease, subcutaneous fluid administration may be required during the period of the study. This is necessary to offset the stress of hospital visits and procedures necessary during the study. If your cat is not currently on SQ fluids, a minimum of twice weekly therapy is required. This should be initiated at least two weeks before beginning stem cell therapy to allow an accurate baseline labwork to be obtained.

What does the study involve?

Stem cells that have been grown from the adipose (fat) of young healthy specific-pathogen free cats (the cats are not harmed during the collection process) will be injected into the retroperitoneal space (area around the kidney) via ultrasound guidance. When this procedure is performed, your kitty will require a mild, fast-acting sedative which is reversed after the procedure.

Blood and urine tests (CBC, biochemistry, urinalysis and urine protein-creatinine ratio) will be performed immediately before the retroperitoneal injection, and again 2 weeks and one month after the injection. In addition, at the beginning and end of the study, a GFR (glomerular filtration rate) will be performed to better document your cat's kidney function. This test involves intravenously injecting a substance (Tc99m nuclear isotope) that is cleared through the kidneys and then imaging your cat under a special camera. When this test is performed, your kitty will require a mild, fast-acting sedative which is reversed after the procedure.

What are the risks?

This procedure has already been performed in normal cats, who have had no major complications, however, there is still a slight risk of discomfort at the site of injection as well as lethargy after sedation from the procedure.

As these stem cells are from another cat, one might expect that there is an immune reaction to the cells. However, allogeneic (transfer between individuals) stem cell therapy is current being performed in many species, including humans, with no obvious sign of the body rejecting the stem cells. It is important to know that if your cat experiences decompensation of its kidney disease and requires hospitalization, we are unfortunately unable to cover the cost of this event due to the financial limitations of the study.

We do not anticipate there to be risk associated with the GFR test, but if your cat poorly tolerates this procedure (slow recovery), you do have the option to withdraw from participation in this procedure.

Is there compensation for your participation?

The cost of preparing the stem cells as well as all costs of visits, labwork and injections are graciously covered by Frankie's Fund for Feline Stem Cell Research, provided your cat is able to travel to CSU for the study. If your cat develops other illnesses unrelated to the treatment, the study will also not be able cover those costs, nor can the study cannot cover the costs of ancillary treatments for kidney failure that your cat may already be receiving or may need to receive in the future.

Owner Consent

I have read the explanations of the study provided above and I understand the above stated conditions and I agree to allow my cat to undergo the procedures described above. If I have any concerns or questions related to this study I should contact Dr. Jessica Quimby at (970) 297-5000 or jquimby@colostate.edu.

Signed: _____

Date: _____

Witness: _____