

Pivotal Clinical Field Study To Evaluate The Safety And Effectiveness Of Capromorelin On Weight Management In Cats With Chronic Kidney Disease

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Appetite stimulation in cats with chronic kidney disease

Inappetance and weight loss is a major contributing factor for cat owners when deciding to euthanise their pet¹. This study² evaluated the safety and efficacy of capromorelin (Eluracat™) in cats with chronic kidney disease (CKD) and unintended weight loss.

Multi-center, placebo-controlled, double-blinded study conducted in 176 cats with CKD that had at least 5% loss of body weight (BW)².

Cats randomised using a 2:1 ratio: 118 cats received capromorelin at 2mg/ kg SID (treatment group) and 58 cats received a vehicle control SID (control group) for 56 days.

Efficacy measured percentage change in BW over time. Primary endpoint was percent change in BW from Day 0 to Day 55. Secondary endpoints defined as:

- percent change in BW from Day 0 to Day 15 and Day 0 to Day 27
- success evaluation at Day 55 (success = percent change in weight \geq 0%)

Adverse reactions captured using owner diary observations, physical examinations and clinical pathology.

By Day 55, the treatment group had a 5.2% increase in BW compared to baseline, with a \pm 6.8% difference compared to control group ($p < 0.0001$).

At Day 15, the treatment group showed a significant weight gain of 3.3% ($p = 0.0002$), while the control group had no change in BW. At day 27, the treatment group had a 3.8% BW increase, while the control group had a decrease of 0.9% compared to baseline ($p < 0.0001$). Overall, more than 80% of cats receiving capromorelin maintained or gained weight.

With respect to adverse effects, capromorelin was well tolerated when compared to the control group, with transient hypersalivation being the only side effect occurring more commonly in the treatment group.

Capromorelin administered at 2mg/ kg SID for 56 days is safe and effective in managing weight loss in cats with CKD.

References:

1. Freeman L.M. Cachexia and Sarcopenia: Emerging Syndromes of Importance in Dogs and Cats, *Journal of Veterinary Internal Medicine*. 2012;26:3–17.
2. Elanco pivotal field study AT002-FCL-16-004, data on file.