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Safety and effectiveness of a single and repeat intramuscular injection of a GnRH vaccine (GonaCon™) in adult female domestic cats

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Sterilization is a key strategy to reduce the number of domestic cats (Felis silvestris catus) entering and killed in shelters each year. However, surgical sterilization (i.e., spaying and neutering) is expensive, labor-intensive, and cannot fully address the 70 million free-roaming cats estimated to exist in the United States alone. GonaCon is a gonadotropin-releasing hormone (GnRH) vaccine developed by scientists at USDA’s National Wildlife Research Center for use as a wildlife immunocontraceptive. An earlier formulation was tested in domestic cats and found to be safe and effective for long-term contraception (median = 39.7 months) with a single dose.1 A newer EPA-registered formulation consists of a different antigen-carrier protein and increased antigen and adjuvant concentrations. There are reports in other species, including the dog, of pronounced and painful vaccine reactions soon after vaccine administration. Thus, a pilot study in cats was undertaken to assess the safety of the newer formulation. The objectives of this study were to (1) evaluate the short-term safety of a single GonaCon immunization in domestic cats, (2) assess the safety consequences of vaccinated cats receiving a second injection of Gonacon (to mimic the accidental revaccination of a cat in the field), and (3) determine the humoral immune response to GonaCon immunization in domestic cats. A total of nine spayed females were used in the study, with three cats per study group (A and B), plus three untreated cats to serve as negative controls for the GnRH antibody titer assay. During Phase 1 of the study (months 1 and 2), cats in Group A received a single intramuscular (IM) injection of GonaCon (0.5 ml) and Group B received a single IM injection of saline (0.5 ml). During Phase 2 (months 3 and 4), Group A received a second GonaCon injection and Group B received their initial GonaCon injection. Titers were measured by ELISA and expressed as a sample to positive ratio. All cats developed GnRH antibodies within 30 days of vaccine administration. The endpoint titer (1:1,024,000) was similar among all cats and levels remained high throughout the duration of the study (i.e., 6 months for Group A, 4 months for Group B). One case of transient edema was noted at 18 days post-injection (Group B). Four cats developed a soft tissue mass at the site of injection: two from Group A and two from Group B. The mean number of days to mass development was 110.3 (range, 18–249 days). Consistent among the four cats, no signs of inflammation, pain, or difficulty ambulating were observed. Similar to Levy et al.’s report1 of later onset injection site reactions, the mass sizes waxed and waned but draining lesions did not develop. In conclusion, this preliminary study suggests that the new GonaCon formulation is safe for continued testing in domestic cats, an accidental revaccination should not increase the risk or severity of a vaccine reaction, and the current formulation effectively elicits a strong humoral immune response. This study represents an important first step towards obtaining regulatory approval to use this vaccine in free-roaming cat populations. If approved, GonaCon will represent the first pharmaceutical product developed specifically to help reduce unowned and feral cat populations. This study was funded in part by the Alliance for Contraception in Cats & Dogs and the Joanie Bernard Foundation.


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