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Masitinib is safe and effective for the treatment of canine mast cell tumors.

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BACKGROUND: Activation of the KIT receptor tyrosine kinase is associated with the development of canine mast cell tumors (MCT). HYPOTHESIS/OBJECTIVE: To evaluate the efficacy of masitinib, a potent and selective inhibitor of KIT, in the treatment of canine MCT. ANIMALS: Two hundred and two client-owned dogs with nonmetastatic recurrent or nonresectable grade II or III MCT. METHODS: Double-blind, randomized, placebo-controlled phase III clinical trial. Dogs were administered masitinib (12.5 mg/kg/d PO) or a placebo. Time-to-tumor progression (TTP), overall survival, objective response at 6 months, and toxicity were assessed. RESULTS: Masitinib increased overall TTP compared with placebo from 75 to 118 days (P = .038). This effect was more pronounced when masitinib was used as first-line therapy, with an increase in the median TTP from 75 to 253 days (P = .001) and regardless of whether the tumors expressed mutant (83 versus not reached [P = .009]) or wild-type KIT (66 versus 253 [P = .008]). Masitinib was generally well tolerated, with mild (grade I) or moderate (grade II) diarrhea or vomiting as the most common adverse events. CONCLUSIONS AND CLINICAL IMPORTANCE: Masitinib is safe and effective at delaying tumor progression in dogs presenting with recurrent or nonresectable grade II or III nonmetastatic MCT.

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