1. Prev Vet Med. 2014 Jul 1;115(1-2):56-63. doi: 10.1016/j.prevetmed.2014.03.010. Epub 2014 Mar 22.

# A single-centre, open-label, controlled, randomized clinical trial to assess the preventive efficacy of a domperidone-based treatment programme against clinical canine leishmaniasis in a high prevalence area.

Sabaté D[1], Llinás J[2], Homedes J[3], Sust M[4], Ferrer L[5].

Author information:

- [1]Department of Research and Development, ESTEVE veterinaria, Lab. Dr. ESTEVE, S.A. Avda. Mare de Déu de Montserrat 221, CP 08041 Barcelona, Spain. Electronic address: dsabate@esteve.es.
- [2]Hospital Veterinario Valencia Sur, Av. Picassent 28, CP 46460 Silla, Valencia, Spain.
- [3]Department of Research and Development, ESTEVE veterinaria, Lab. Dr. ESTEVE, S.A. Avda. Mare de Déu de Montserrat 221, CP 08041 Barcelona, Spain.
- [4]Department of Clinical Research, Lab. Dr. ESTEVE, S.A. Avda. Mare de Déu de Montserrat 221, CP 08041 Barcelona, Spain.
- [5]Department of Clinical Sciences, Tufts Cummings School of Veterinary Medicine, 200 Westboro Road, North Grafton, MA 01536, United States.

**Abstract**

The innate immune response acting immediately after initial infection with Leishmania parasites is known to play a relevant role in prevention against clinical progression of the disease. Domperidone is a dopamine D2 receptor antagonist that has shown to enhance the innate cell-mediated immune response. The aim of this study was to assess the preventive efficacy of a domperidone-based treatment programme against clinical canine leishmaniasis (CanL) in a high prevalence area. The study was performed with 90 healthy, seronegative dogs of different sex, age, weight and breed from a single veterinary clinic located in Valencia (Spain). Dogs were randomly allocated into two groups. Dogs in one group (domperidone-treated group; n=44) were administered an oral suspension of domperidone at 0.5 mg/kg bw/day during 30 consecutive days, every 4 months. Dogs in the other group (negative control group; n=46) were left untreated. A 21-month follow-up period was implemented covering two seasonal phases of the sand fly vector. During this period all animals underwent periodic clinical examinations and blood samplings for anti-Leishmania serological testing. Dogs seropositive for Leishmania (IFAT antibody titre≥1:80) plus at least one clinical sign consistent with CanL (indicative of active infection and incipient disease progression) were categorized as a 'prevention failure'. These dogs were withdrawn from the study after confirming the infection by direct observation of the parasite in smears of lymph nodes and/or bone marrow aspirates. The cumulative percentage of 'prevention failure' after 12 months was significantly lower in the domperidone-treated group than in the negative control group (7% versus 35%, p=0.003). Differences between groups persisted after 21 months (11% versus 48%, p<0.001). The prevention rate provided by domperidone was 80% during the first 12 months and 77% throughout the complete 21-month follow-up period, with odds ratios of 7.3 (p=0.001) and 7.15 (p<0.001), respectively, this indicating that the risk for domperidone-treated dogs to develop the clinical disease is quite 7 times lower than for dogs left untreated. The results of this study demonstrate that the implementation of a strategic domperidone-based treatment programme consisting in quarterly repeated 30-day treatments with domperidone effectively reduces the risk to develop clinical CanL in areas with high prevalence of the disease.



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