

# CLINICAL EFFICACY OF A DOMPERIDONE-BASED TREATMENT PROGRAM FOR THE PREVENTION OF CANINE LEISHMANIOSIS

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## INTRODUCTION

Repeated administration of a dopamine D2 receptor antagonist, domperidone, to healthy animals progressively increases the phagocytic activity of neutrophil and monocyte peripheral blood populations leading to an increased resistance of these cells against *in vitro* experimental infection

with *Leishmania* amastigotes (unpublished data). **This confers domperidone a potential use for prevention of canine leishmaniosis**, in addition to its already reported clinical efficacy in the treatment of naturally diseased animals (Gómez-Ochoa P *et al.* 2009, Oliva G *et al.* 2010).

## OBJECTIVE

The aim of the study was to assess the efficacy of a treatment program based on domperidone for the prevention of canine leishmaniosis under real field conditions.

		Treated Group	Control Group	p value
<b>Sex</b> (n and %)	Males	25 (56.8%)	25 (54.3%)	0.981 (1)
	Females	19 (43.2%)	21 (45.7%)	
<b>Age</b> (years)	mean (SD)	5 (2.2)	5 (2.3)	0.595 (2)
	range	1-10	1-10	
<b>Weight</b> (kg)	mean (SD)	20.3 (10.83)	20.4 (8.46)	0.683 (2)
	range	6.5 - 54	7 - 43	
<b>Breed</b> (n and %)	Mongrel	13 (29.5%)	23 (50.0%)	0.606 (3)
	Other*	31 (70.5%)	23 (50.0%)	

\* up to 24 different breeds  
(1) Pearson chi-square test  
(2) Student's T-test  
(3) Mann-Whitney Rank Sum test

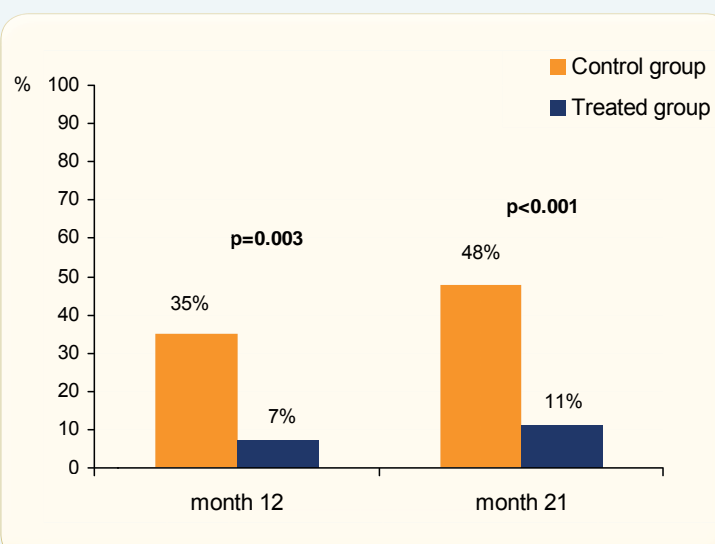
**Table 1.** Distribution of animal baseline characteristics and analysis of homogeneity between the two groups.

## MATERIAL AND METHODS

- Ninety clinically healthy dogs, serologically negative to *Leishmania* (IFAT < 1/40), living in a highly endemic geographic area in Valencia (Spain) were included, with the consent of their owners, in a clinical trial performed under the authorization of the Spanish Medicines Agency (AEMPS).
- Dogs were randomly distributed in two homogenous groups (Table 1):
  - Treated group** (n=44)  
Oral suspension of domperidone at 0.5 mg/kg/day during 30 consecutive days, on a 4-monthly basis, with the first treatment being started at the beginning of the *Phlebotomus* season.
  - Control group** (n=46)  
Non-treated.
- No other treatment nor insect repellents were used.
- 21-month follow-up period with periodic clinical examinations and serological determination of anti-*Leishmania* antibody titers.
- Active infection / disease progression was considered when, at a given examination, a dog showed any clinical sign compatible with the disease + positive anti-*Leishmania* antibody titers (IFAT ≥ 1/80).
- Main parameter = cumulate percentage of dogs with active infection / disease progression up to 12 and 21 months of follow-up.

## RESULTS

- The cumulate percentage of dogs showing active infection / disease progression was significantly lower in the domperidone-treated group both at month 12 and at month 21 of follow up period (Fig. 1).



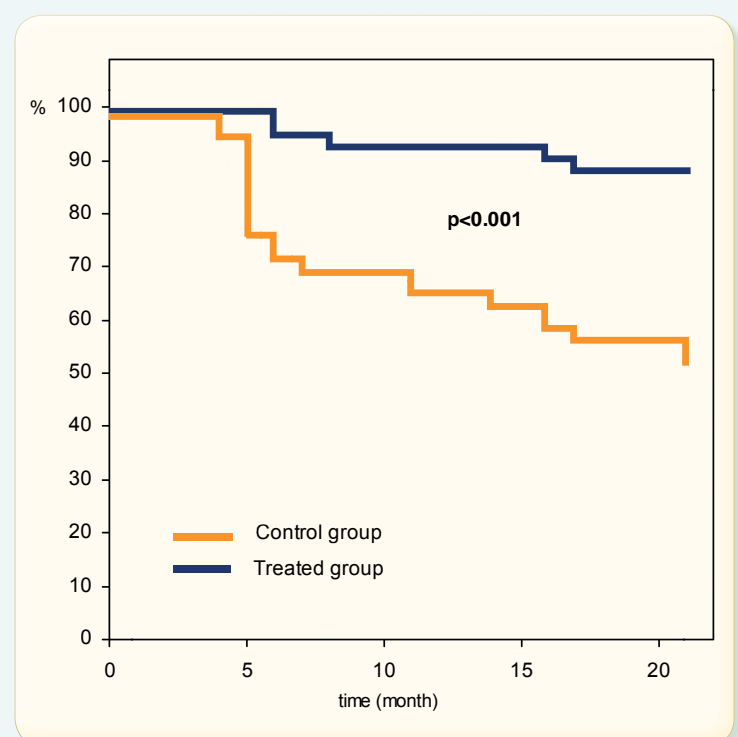
**Figure 1.** Cumulate percentage of diseased dogs and statistical comparisons between groups (Pearson chi-square test).

- Repeated treatment with Domperidone was well tolerated and accepted, with only two dogs showing a transient mild galactorrhea and two other dogs showing soft faeces.

- Dogs treated with domperidone offered a consistent and significantly higher degree of resistance to active infection / disease progression over time (Fig. 2).

**Figure 2.** Evolution (Kaplan Meyer estimates) of percentage of healthy animals in both groups thorough the whole 21-month follow-up period and statistical comparisons (Logrank test).

- The odds-ratios calculated for each period were 7.3 (p=0.001) at month 12 and 7.2 (p<0.001) at month 21, thus indicating that **the overall risk (odds) for Domperidone-treated dogs to clinically develop canine leishmaniosis is quite 7 times lower than for not treated animals.**



## CONCLUSIONS

The results of this study demonstrate that the implementation of a strategic domperidone-based treatment program is highly efficacious in the prevention of canine leishmaniosis in endemic areas.

## REFERENCES