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CLINICAL EFFICACY OF LEISGUARD® FOR THE PREVENTION OF CANINE LEISHMANIOSIS IN AN ENDEMIC AREA WITH LOW RISK OF INFECTION

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OBJECTIVE

The aim of the present study was to evaluate the efficacy of a Leisguard®-based program strategically established for the prevention of canine leishmaniosis in an endemic area with low prevalence.

INTRODUCTION

Leisguard® is a domperidone-based oral solution recently marketed in several European countries for the treatment and prevention of canine leishmaniosis. Its repeated administration to dogs induces activation of phagocytic cells leading to an increase in their anti-*Leishmania* potential (Gomez-Ochoa et al. 2012) being this the rationale of its clinical indications. When administered for preventive use, repeated treatments with Leisguard® have to be strategically scheduled during the year according to the parasite's transmission season and the prevalence of the disease in a given geographical area (Llinás et al, 2011).

MATERIAL AND METHODS

- Two hundred and forty clinically healthy dogs of different sex, age, weight and breed, serologically negative to Leishmania (Direct Agglutination Test, DAT<1/400), were included in a controlled, randomized clinical trial performed under the authorization of the Spanish Medicines Agency (AEMPS).
- Dogs were housed in open-air premises in a dog kennel located in Valladolid (Spain) with a seroprevalence reported to be around 7%.
- Dogs were randomly distributed in two homogenous groups:

  Treated group (n=120):

  Prevention program consisting of two 30-day treatments with Leisguard® at 1ml/10kg/24h, at the beginning and at the end of the Phlebotomus season (May/June – September/October).

  Control group (n=120):

  Non-treated.

- No other preventive treatment or insect repellents were used during the study.
- 9-month follow-up period with periodic clinical examinations and serological determinations of anti-*Leishmania* antibody titers performed at the end of the study (January-February) or when compatible clinical signs were found.
- Active infection / disease progression was considered when, at a given examination, a dog showed any clinical sign compatible with the disease and positive anti-*Leishmania* antibody titers (DAT≥1/400).
- Main parameter = cumulate percentage of dogs with active infection / disease progression at the end of the study.

RESULTS

- All animals under the Leisguard®-based program remained healthy and seronegative to Leishmania up to the end of the 9-month follow-up period (Figure 1).
- In contrast, seven dogs out of 120 in the Control group were seropositive to *Leishmania* (DAT>1/400) at the end of the study and had developed clinical signs compatible with canine leishmaniosis (peripheral lymphadenomegaly and alopecia) during the last month of the study, thus indicating active infection and disease progression.

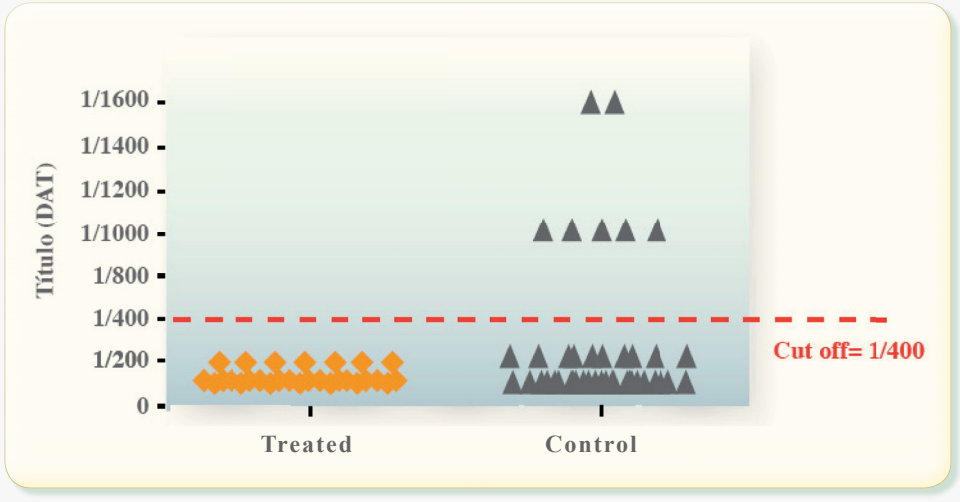

Figure 1. *Anti-Leishmania antibody titters' distribution in both groups, up to the end of the study (Direct Agglutination Test, cut-off titter <1/400).*

- The presence of the parasite was confirmed in all seropositive animals by means of direct visualization in lymph node or bone marrow aspirates.
- Differences between groups in terms of incidence of the disease were statistically significant (0% vs 5.83% in the Treated and Control groups, respectively; p<0.001) (Figure 2).

	Diseased	Healthy	p-value*
Control group (n=120)	7 (5,8%)	113 (94,2%)	< 0,001
Treated group (n=120)	0 (0%)	120 (100%)	

** Pearson's Chi-squared test.*

Figure 2. *Distribution of Diseased/Heathy dogs at the end of the study.*

- Leisguard® was well accepted by all dogs and no adverse reactions were reported during the study.

REFERENCES

Llinás J, Gómez-Ochoa P, Sabaté D, Homedes J and Ferrer, L. Clinical efficacy of a domperidone-based treatment program for the prevention of canine leishmaniosis. Proceedings of the 46th AVEPA-SEVC Congress, 2011.

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CONCLUSIONS

The results of this study confirm the excellent efficacy and safety of Leisguard® when administered for the prevention of canine leishmaniosis according to an strategically established program for endemic areas with low risk of infection.