Safety assessment of a single and a repeated dose administration of the inactivated vaccine ERAVAC® in dwarf pet rabbits.

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INTRODUCTION AND STUDY DESIGN:

The main objective of this study was to evaluate the safety and serological response of ERAVAC® (HIPRA, Spain), an inactivated vaccine for preventing the new variant of rabbit haemorrhagic disease virus (RHDV-2), when administered into dwarf pet rabbits.

The study was conducted with sixteen 30-day-old Toy dwarf rabbits, the minimum age recommended for vaccination. The rabbits were randomly distributed into vaccinated and control groups. Eleven rabbits were assigned to the vaccinated group and were immunized subcutaneously with ERAVAC® according to the established vaccination plan with a single 0.5 ml dose. Five rabbits consisted the control group and received 0.5 ml of PBS (phosphate buffer solution) with the same plan and route of administration as a placebo. After 14 days of observation, all the rabbits were vaccinated with another 0.5 ml dose of ERAVAC® or PBS (vaccinated or control group) subcutaneously as a repeated dose and were observed for another 21 days.

Safety assessment was based on the observation of abnormal local and general reactions after both, the single and the repeated dose administration. Moreover, the rectal temperature was recorded one day before vaccination, at the moment of vaccination, four hours post-vaccination and then daily for 4 days.

In addition to the safety assessment, serological parameters were also analysed in both, vaccinated and control groups, on day 35 post-vaccination (D35). Serological response was evaluated by in-house competition ELISA against RHDV-2 for the new variant.

RESULTS:

Local and general clinical signs:

Two vaccinated animals showed local reactions during the study. One animal presented 1 nodule (<2 cm in diameter) at day 14 (D14) before the administration of the repeated dose. Another animal presented an inflammation at the site of injection (<2 cm in diameter) at day 14+4h (D14+4) that was spontaneously resolved in less than 24 hours.

None of the animals showed general clinical signs during the entire study (14 days of observation after the single dose administration and 21 days of observation after the repeated dose administration).

Rectal temperature:

Rectal temperature from all the animals was recorded on the day before vaccination, the day of vaccination, after 4h of vaccination and daily for 4 days at the single and repeated dose administration.

No significant rectal temperature differences between both groups (vaccinated and control) were observed after the single and the repeated dose administration (Figure 1). The average of rectal temperatures per group and the individual rectal temperature records remained under 40.1ºC during the registration periods of the entire study, indicating that they were in the physiological range described by Merck Manual (38.6-40.1ºC).

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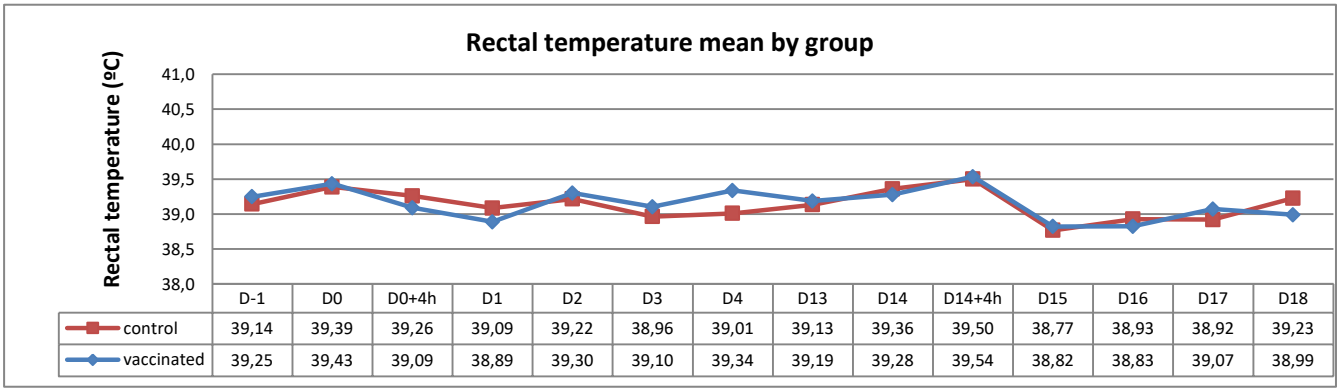

	D-1	D0	D0+4h	D1	D2	D3	D4	D13	D14	D14+4h	D15	D16	D17	D18
control	39,14	39,39	39,26	39,09	39,22	38,96	39,01	39,13	39,36	39,50	38,77	38,93	38,92	39,23
vaccinated	39,25	39,43	39,09	38,89	39,30	39,10	39,34	39,19	39,28	39,54	38,82	38,83	39,07	38,99

Figure 1. Average of rectal temperature per group after the single dose administration (D0= day of vaccination) and the repeated dose administration (D14). T-test was used to analyse differences between groups at each time point (p>0.05).

Serological response:

All rabbits were antibody negative to RHDV-2 prior to vaccination, and the control group remained seronegative throughout the post-vaccination period. On the other hand, the 100% of the vaccinated animals seroconverted after the administration of ERAVAC®. Serological parameters are detailed in Table 1.

Animal ref.	Group	D35
9823	Vaccinated	>640
9825		>640
9827		>640
9835		>640
9837		>640
9839		>640
9843		>640
9851		>640
9853		>640
9857		>640
9859		160
% positive animals		100%

Animal ref.	Group	D35
9821	Control	N
9829		N
9833		N
9841		N
9847		N
% positive animals		0%

Table 1. Serological results on Day 35 after vaccination (N = negative).

CONCLUSIONS:

This study showed that vaccination against RHDV-2 with the licenced vaccine ERAVAC® given to 30-day-old Toy dwarf rabbits generates in a low rate transient local signs, while no general signs or important rectal temperature fluctuations were observed. These results suggest that the administration of ERAVAC® in dwarf pet rabbits can be considered safe in terms of local and general reactions. Moreover, all vaccinated animals responded serologically to ERAVAC® vaccination inducing high antibody response compared to the negative response in the control group.

BIBLIOGRAPHIC REFERENCES:

Manual Merck: Adapted from Robertshaw D. *Temperature Regulation and Thermal Environment*, in Dukes' Physiology of Domestic Animals, 12th ed., Reece WO, Ed. Copyright 2004 by Cornell University.