Safety assessment of a single and a repeated dose administration of YURVAC® RHD vaccine in dwarf pet rabbits

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Introduction

Dwarf rabbits are considered the most sensitive category of rabbits since their body weight is significantly lower than other rabbits, but the dose administered is the same. Hence, with the intention to demonstrate the safety of YURVAC® RHD in the most sensitive category of rabbits, dwarf rabbits were chosen for this study. The safety administration of a repeated dose was also assessed in the present study in order to demonstrate the safety of the possibility of the revaccination.

Material and Methods

The animals free from antibodies against RHDV and RHDV2 (HI, hemagglutination inhibition assay) were divided into two groups: a group of 10 rabbits which were vaccinated with YURVAC® RHD by subcutaneous route according to the established vaccination plan with a single dose (0.5 ml) and a repeated administration of one dose 14 days later; and a control group of 6 rabbits which were administered the same volume of phosphate buffer solution (PBS) following the same schedule, in order to compare the safety parameters between both groups. After the single dose administration and the repeated dose administration, all animals were observed in order to record any abnormal local or general clinical signs. The rectal temperature of the rabbits was recorded one day before vaccination, at the time of vaccination, four hours post-vaccination and then daily for 4 days. The animals were observed after the repeated dose administration for 21 days. Serological levels for RHDV2 antibodies (HI) were evaluated at vaccination and at the end of the study.

Results

None of the animals showed general clinical signs during the 14 days of observation after the single dose administration and after the 21 days of observation following the repeated dose administration. Three vaccinated animals showed local reactions during the study after the administration of the repeated dose. This inflammation was <2cm and disappeared 24 hours after its observation. Regarding the rectal temperature of the animals, all were within physiological ranges during the study[1]. None of the mean rectal temperature increase exceeded 0.44ºC and none of the animals showed a temperature increase greater than 1.15ºC (*Figure 1*). No differences in mean body weight between groups were detected at any time of the study. This confirms that the administration of YURVAC® RHD vaccine do not affect the normal body weight performance. All vaccinated animals seroconverted by Day 35 after second vaccination, while all the control animals remained negative for RHDV and RHDV2 antibodies (*Figure 2*).

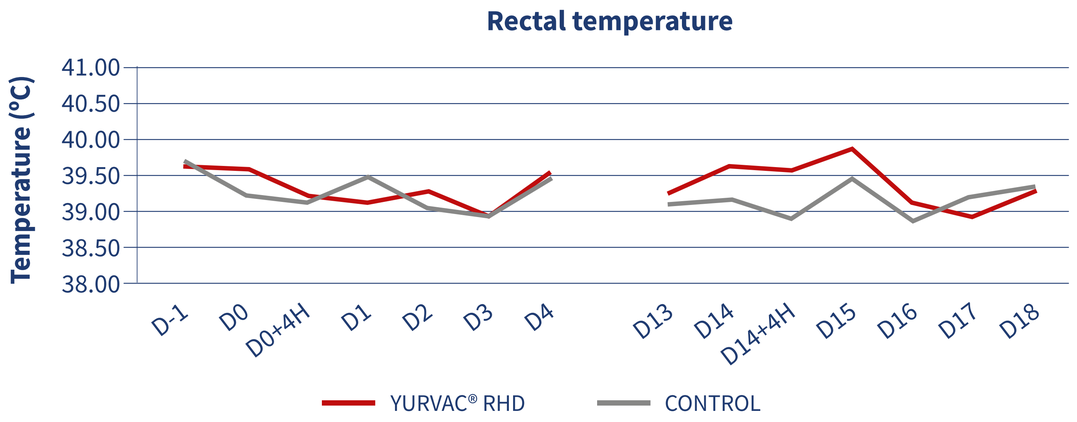

Figure 1: Average rectal temperature per group after single dose administration (D0) and after the repeated administration of one dose (D14).

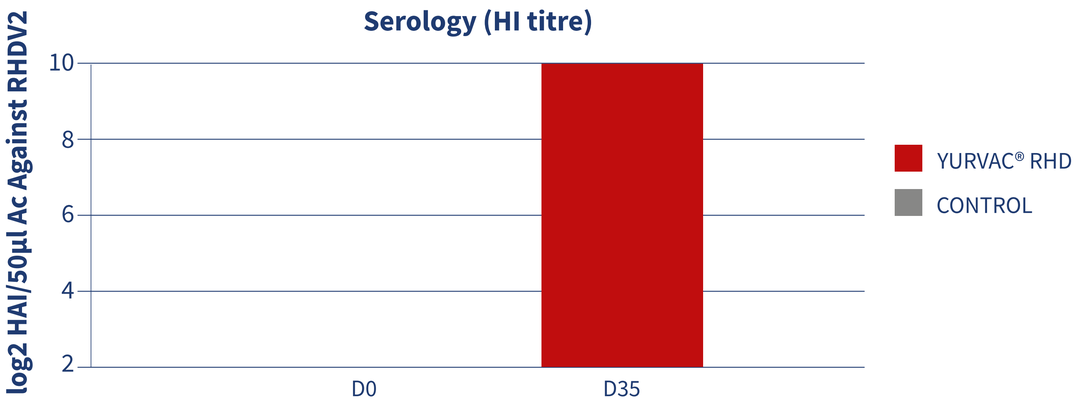

Figure 2: Serological response against RHDV2 on the day of vaccination (day 0), and at the end of the study (day 35). Animals with log2 HAI/50 µl ≥ 3 are considered seropositive.

Conclusions

The results of this study have shown that YURVAC® RHD vaccine is a safe vaccine. None of the animals showed general clinical signs during the 14 days of observation after the single dose administration and after the 21 days of observation following the repeated dose administration. The slight inflammation observed after the repeated dose disappeared 24 hours after its observation. YURVAC® RHD did not affect rectal temperature when administered to dwarf rabbits, considered the most sensitive category of rabbits. No differences in mean body weight between groups were detected at any time of the study. This confirms that the administration of YURVAC® RHD do not affect the normal body weight performance. At the end of the study, the serological levels for RHDV2 antibodies were determined and high titres were observed in the vaccinated group and no RHDV2 antibodies in the control group, indicating an adequate vaccination administration to all the vaccinated animals.

References

1. 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.