Pre-Clinical Evaluation of VAX-ID[®]

A Device for Standardized, Accurate, and User-Independent Intradermal Vaccination

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INTRODUCTION

The abundance of antigen-presenting cells in the skin makes it a desirable target for vaccine administration. Intradermal (ID) injection is routinely administered with the Mantoux technique, but this technique has been known to present several difficulties in administration. VAX-ID[®] is a state-of-the-art device for intradermal injection developed by Idevax BV, which allows for skin vaccination with standardized, accurate, dose-sparing, and user-independent features. VAX-ID[®] is therefore well-situated for use in mass vaccination campaigns, and for administering vaccines that are expensive or in short supply. VAX-ID[®] has evolved from generation 1 (VAX-ID[®]2000) to generation 2 (VAX-ID[®]2200). An in vivo study has been conducted to provide evidence on the performance and safety of VAX-ID[®] in a living system.





Figure 3: VAX-ID[®], Intradermal injection device.

RESULTS & DISCUSSION

Visual inspection showed bleb formation in 74% of the samples evaluated, and the average bleb diameter was 0.56cm. Bleb formation is considered as a sign of successful ID injection. ID injection using VAX-ID[®] showed dye deposition mainly in the dermis reaching both the papillary and reticular dermis.

Those came in support of the performance of the second generation of VAX-ID[®]. Transient erythema was observed at the injection site, micro bleeding was only noticed in two samples, and macro bleeding was not observed in any of the samples, indicating VAX-ID[®] is safe for ID injection.

MATERIALS & METHODS

A total of two piglets received 19 injections with the VAX-ID[®] device, containing a 32G needle. An injection of NaCl 0.9% and Chinese Ink 1:0.15 ratio was injected in 3 sites: the neck, back, and abdomen. The injection sites were immediately visually inspected to evaluate safety results through local adverse effects and performance through bleb formation. The piglets were next euthanized, tissue samples were collected and immediately fixed in a 4% buffered formalin solution. The samples were stained with hematoxylin and eosin (H&E) for histological analysis.





Figure 4: Piglet skin dye deposition post injection with VAX-ID[®] 32G. H&E stain 20x.

CONCLUSION

This study demonstrated the effectiveness and safety of the use of VAX-ID[®] for intradermal injection purposes. VAX-ID[®] containing a

2 female piglets 12 kg

19 VAX-ID injections injection sites inspection and at 3 sites samples taken for histology

Figure 2: Study methodology and materials

32G needle was able to successfully inject the dye in the dermal layer of the skin, as confirmed by the histological evaluation. The device induced bleb formation after injection, indicating a successful intradermal injection. No serious adverse events were observed.

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histological examination