OBJ LIMITED
Active transdermal drug delivery

Trial Summary| Transdermal Vaccination

Dermaportation Delivered Sheep Vaccination

Objective

Transdermal drug delivery avoids gastric degradation and hepatic first pass metabolism encountered with the oral delivery route, and eliminates pain associated with the injectable route. Many transdermal technologies are constrained by the molecular size of their targets. OBJ has developed a novel transdermal drug delivery technology, Dermaportation, which has been shown to transdermally deliver a broad range of molecules and molecular weights. Here, the efficacy of Dermaportation is assessed for delivering GLANVAC™ vaccine in sheep.

Method

Subjects: 8 Merino whethers (desexed male sheep, 12 months) were randomly assigned to Dermaportation enhanced topical vaccination, or intramuscular vaccination. Animal care was according to protocols and guidelines approved by the European Communities Council Directive of 24 November 1986 (86/609/EEC).

Vaccination: Four days before the first treatment, a section of wool (10cm x 10cm) was shorn for the topical vaccination. The fleece was left intact. The sheep assigned to the Dermaportation treatment had the Dermaportation device strapped on the clipped areas on their backs. Through a hole in the middle of the Dermaportation coil, 2mL GLANVAC™ was poured, and the Dermaportation system was activated for 30 min. The control group received an intramuscular injection of 2mL GLANVAC™.

Samples: Ten (10) mL blood samples were collected (jugular vein; into vacutainer with sodium citrate) at 1 week before vaccination, 2 weeks after, and 2 weeks post booster vaccination. The period between vaccination and booster was 4 weeks. Samples were centrifuged and the plasma frozen (-20°C) for subsequent analysis to establish background antibody levels. The extent of anti-body production was measured using a colorimetric immuno-assay. GlANVAC™ was pipetted into wells of a Nunc maxi-sorb plate, which was subsequently rinsed and then the plasma added. The proteins were allowed to adsorb for 10 min, and then the wells were rinsed. Subsequently, a solution of rabbit anti-sheep IgG conjugated with alkaline phosphatase was pipetted into the wells (10min). The activity of the alkaline phosphatase was measured using t p-nitrophenyl phosphatase. The alkaline phosphatase activity was measured at 450nm absorbance and analyzed statistically.

Result

The Dermaportation treated group had a similar immune response (total IgG) to the intramuscular group (Figure 1). The within subjects delta scores showed that the Dermaportation treated group had a significant increase in immune response due to the two topical treatments ($p < 0.01$).

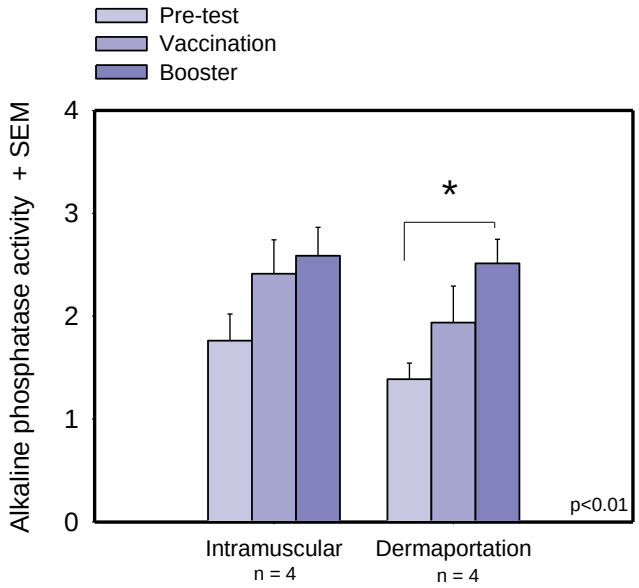

Figure 1: *The immune response of sheep to Dermaportation-enhanced topical vaccination is similar to the immune response to intramuscular vaccination. Blood samples were taken before vaccination, 2 weeks after, and 2 weeks post booster vaccination.*

Summary

Dermaportation was successful at immunizing sheep with the GLANVAC™ vaccine through the skin. Moreover, Dermaportation was as effective as the standard intramuscular injection. The Dermaportation effect was strong enough to demonstrate efficacy on total IgG in a small number of animals, which had not received previous vaccination.