

Immune Protection Comparison Trial Draft Experimental Design 1/28/05

Purpose: Determine the effect of a single treatment dose of PRRS prevention test material on reproductive disease and virus transmission preweaning and postweaning.

Hypothesis: Previous exposure to PRRS antigens prevents reproductive disease and virus transmission in offspring following virulent challenge late in gestation. Assumes the naïve, late gestation gilt is the most susceptible form of swine to disease manifestations of PRRS.

Experimental plan: Phase 1. Gilts will be divided into treatment groups at random with the following groups and numbers. (1) No treatment and no challenge (n=20). (2) No treatment and virulent challenge (n=50). (3) Treatment (single mixture of all live materials) and no challenge (n=50). (4) Treatment_{1...x} and virulent challenge (n=100 for 1...x). Variation in control groups (1) and (3) is expected to be low, so group sizes do not need to be so large. Variation in group (2) is expected to be greater, so a larger size is needed. Variation in groups in (4) is expected to be highly variable so the group size needs to be as large as possible.

Treat gilts with test materials prebreeding sometime between 70 and 150 days of age. Take blood sample before and 30 days after treatment to determine if (a) animals were negative at the start and (b) to determine the immunological response to treatment as measured by level of antibody. ELISA would be performed for nucleocapsid, nsp2, and mixture of endodomains and ectodomains of GP5 and M.

Breed gilts and challenge pregnant animals at 90 days of gestation with a moderately to severely virulent recent strain by the intramuscular route at a dose of about 10^5 TCID₅₀. Take a blood sample before challenge to determine the immunological status of the animal as measured by level of antibody.

Animals will farrow and the following data collected:

(A) Collect all farrowing data for direct reproductive disease effects.

(B) Bleed piglets at day 3 to determine antibody levels and virus levels. Antibody may or may not be maternal since the Butler lab has shown that antibodies to PRRSV can be made in fetal life.

(C) Wean at 21 days and collect blood at 21 (or 28?) days to measure exposure to virus based on antibody levels and level of virus (21 days). Collect health and growth information for direct protective effects.

(D) Cross foster negative piglets at 3-7 days post-farrowing and follow them to weaning to look for transmission within the litter.

(E) Move piglets by treatment group into the nursery with naïve sentinels (n=20). Monitor for 21 (?) days for response over time for direct infection (viremia) and evidence of exposure (antibody response)