

Basic Clinical Trial Design and Considerations for Conducting On-Farm Evaluations of Complementary Therapy

Ynte Schukken, DVM, MS, PhD and Linda Tikofsky, DVM

Summary

This presentation will describe the basic ideas of evaluation of new therapies for diseases in cows. We will discuss the need for a proper study design, objective outcome measures and basic statistical methods to compare treatments with control groups. The need for randomized clinical studies will be advocated.

Evaluation of treatments for disease of cows

Treatments can be evaluated using several different options. Probably the simplest and least trustworthy is a series of case studies. In such a situation, 'stories' of successful cases are presented and the user needs to have great confidence in the 'storyteller' to believe the reported success. A better argument can be made if two different treatments are compared. Existing data on the two treatments could be evaluated and if a difference exists then the argument can be made that one treatment is better than the next. Although this is a comparative study, the argument could be made that one treatment was used in a more favorable group of animals with regard to outcome (for example younger animals with less previous disease). It is often difficult that eliminate all possible biases from such studies. For this reason randomized clinical trials were designed:

The gold standard for showing efficacy of therapeutics is to perform a double blind randomized clinical trial. The characteristics of such a study are: 1) presence of two or more treatment protocols that are compared (one of the protocols could be no treatment or a placebo treatment), 2) random allocation of treatment protocol to a patient, 3) unbiased measurements of success and 4) blocking of patients to ensure that the two treatment groups are more or less equal with regard to important factors such as age of the animals and days in milk.

Considerations for on-farm randomized controlled treatment studies

When designing on-farm randomized controlled treatment studies it is important to keep a few principles in mind:

- The study should have a clearly defined objective. Probably the most valuable objective for a treatment trial in organic dairies is 'show that the new treatment is equal or better than the control treatment (often no treatment or a placebo)'.
- The study should have sufficient sample size so that the conclusions can be drawn with a large confidence.
- The measurement of treatment success should be objective and not subject to observer bias. So, consistent low somatic cell counts is better compared to 'the cow looks healthy'.
- On-farm trials have the great benefit that they involve real life patients. The validity of such studies is very high. They provide a better validity compared to trials in 'university herds' or experimental animals.