Sveriges lantbruksuniversitet
Swedish University of Agricultural Sciences

SLUkurs

Syllabus

PVS0120 Construction of the trial protocol for Controlled Clinical trials, 1.0 credits

Syllabus approved

2015-03-19

Subjects

Animal Science

Education cycle

Third cycle

Grading scale

Pass / Failed
The requirements for attaining different grades are described in the course assessment criteria which are contained in a supplement to the course syllabus. Current information on assessment criteria shall be made available at the start of the course.

Language

English

Prior knowledge

Admitted to a postgraduate program in animal science, biology, veterinary medicine, food science, nutrition, nursing, bioinformatics or similar subjects, or to a residency program in veterinary science.

Objective, including learning outcomes

After completion of the course, the student should be able to (all in relation to a proposed controlled clinical trial):

- Formulate the aim
- Define a reference and study population
- Describe the procedure for discontinuation
- Perform stratification
- Define randomization procedure
- Choose the design of the study
- Relevantly discuss factors and variables, study procedure, monitoring plan, statistical analysis plan
- Finalize the draft of the trial protocol

Content

This course is aimed to those of you who plan to conduct research projects. Designing a good project plan will be of crucial significance for creating a project with credible results. The course will review key concepts for scientific experiments, focusing on practical and theoretical design of controlled clinical trials.
The first part will cover the design of the experimental protocol, measurements hypotheses, population and selection, representative sampling, stratification and randomization procedures and study design.
A significant part of the course consists of discussions of the various methods used in the planning of clinical trials, and how these methods are related to statistical models.
Central themes of the course will be: Factors and Variables / Establishment of database / Choice of statistical models / Calculation of "sample size".

Requirements for examination

Active contribution during exercises and discussions. No written exam.

Additional information

Responsible department

Department of Clinical Sciences