



DEPARTMENT OF MATHEMATICAL SCIENCES

MSA620 Design and Analysis of Clinical Trials, 7.5 credits

Design och analys av kliniska försök, 7,5 högskolepoäng

Second Cycle

Confirmation

This course syllabus was confirmed by Department of Mathematical Sciences on 2019-01-21 to be valid from 2019-01-21, spring semester of 2019.

Field of education: Science 100%

Department: Department of Mathematical Sciences

Position in the educational system

The course is part of the Master Program in Mathematical Sciences. It is also open for students outside the program who meet the course prerequisites.

The course can be part of the following programmes: 1) Mathematical Sciences, Master's Programme (N2MAT) and 2) Bachelor's Programme in Mathematics (N1MAT)

Main field of studies

Mathematical Statistics

Specialization

A1N, Second cycle, has only first-cycle course/s as entry requirements

Entry requirements

For entrance to the course, a student is required to have knowledge corresponding to the courses *MSG110 Probability Theory*, *MSG200 Statistical Inference*, *MSG500 Linear Statistical Models* and *MMG300 Multivariable Calculus*.

Learning outcomes

After passing the course the student will be able to

- recognize common study designs in clinical trials and explain their rationale,

- perform statistical analysis appropriate for various designs covered in the course using software packages.

Course content

The course covers the following topics:

- the clinical trial protocol
- sources of bias in clinical trials
- blinding
- randomization
- sample size calculation
- design and analysis of phase I, phase II, phase III, hybrid trials, interim analysis and non-inferiority studies
- stochastic curtailment
- Bayes designs
- administrative issues in study design.

Form of teaching

Lectures, computer exercises and classes.

Language of instruction: English

Assessment

Written final examination. There might be home assignments.

Grades

The grading scale comprises: Pass with Distinction (VG), Pass (G) and Fail (U). The grades are Fail (U), Pass (G), and High Pass (VG). Students who are contractually entitled to ECTS grades should inform the examiner about this no later than one week after the start of the course. Students without such entitlement will not be awarded ECTS grades. Grades will be converted into ECTS terminology according to a standard model approved by the University President.

Course evaluation

Oral and/or written course evaluation will be performed. The results of the evaluation will be communicated to the students and will serve as a guide for the development of the course.