DEPARTMENT OF CLINICAL SCIENCE AND EDUCATION, SÖDERSJUKHUSET

S1F3173, Clinical Trials in Cardiovascular Research, 1.5 credits (hec)

Kliniska prövningar inom kardiovaskulär forskning, 1,5 högskolepoäng

Third-cycle level / Forskarnivå

Approval

This syllabus was approved by the The Committee for Doctoral Education on 2024-09-18, and is valid from spring semester 2025.

Responsible department

Department of Clinical Science and Education, Södersjukhuset, Faculty of Medicine

Prerequisite courses, or equivalent

No prerequisite courses, or equivalent, demanded for this course.

Purpose & Intended learning outcomes

Purpose

To enable doctoral students to:
-Improve their knowledge and skills related to clinical trial planning and design as well as successful running of different types of clinical trials (observational studies,registries, randomized trials);
-Acquire an overview of some recent key trials in the cardiovascular arena.

Intended learning outcomes

After the course, the participants should be able to:
-design a clinical trial
-account for the relevant regulatory aspects involved in the process of designing and running a clinical trial
-analyze and interpret trial data
-critically review literature of clinical trials
-handle important statistical issues (e.g. different types of adjustments for confounders, biases,

how to perform subgroupanalysis in trials, statistical methods for meta-analyses) related to different trial designs (e.g. observational studies,registries, randomized trials and meta-analyses).

Course content

Lectures/Workshops on the following topics:
-Different designs of clinical trials
-Requirements from regulatory agencies and post marketing surveillance
-Upcoming and ongoing cardiovascular clinical trials
-Statistical issues in clinical trials
-How to interpret clinical trials

Forms of teaching and learning

- Lectures/workshops, debates on important clinical trials (2 days)
- Home-based studying and preparation of the exam - group work (2 days)
- Presentation and discussion of your own design of a clinical trial (1 day)

Language of instruction

The course is given in English

Grading scale

Pass (G) /Fail (U)

Compulsory components & forms of assessment

Compulsory components

Participants should attend all the sessions and be involved in group work and presentation of the home assignment. The students who have missed course sessions will be assigned extra-reading and home work to compensate the absence.

Forms of assessment

Home-based group assignment (design of a clinical trial on a topic of students' choice) which will be presented/discussed on the examination date. Each individual will be assessed on the basis of the achievement of the intended learning outcomes of the course.

Course literature

Recommended reading materials will be provided well in advance of the course.