DEPARTMENT OF CLINICAL SCIENCE AND EDUCATION, SÖDERSJUKHUSET

S1F5307, Clinical Trials in Heart Failure Research, 1.5 credits (hec)

Kliniska prövningar vid forskning om hjärtsvikt, 1,5 högskolepoäng

Third-cycle level / Forskarnivå

Approval

This syllabus was approved by the The Committee for Doctoral Education on 2025-02-13, and was last revised on 2025-02-17. The revised course syllabus is valid from autumn semester 2025.

Responsible department

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

Prerequisite courses, or equivalent

Epidemiology I and Biostastics I or equivalent knowledge

Purpose & Intended learning outcomes

Purpose

To enable students to learn the principles of study designs and data analyses/interpretation for clinical trials in heart failure.

Intended learning outcomes

At the end of the course, the participants are supposed to be able to:
- choose the adequate trial design to conduct an interventional study
- apply important ethical principles while designing a clinical trial
- design a clinical trial which satisfies the requirements of the regulatory agencies
- choose and use key statistical methods for running randomized controlled trials and meta-analyses of randomized controlled trials
- critically interpret data from randomized controlled trials and meta-analyses of randomized controlled trials

Course content

The lectures will cover:

1) Key elements in randomized controlled trials design: methods for randomization; differences between superiority and non-inferiority trials; different types of endpoint analysis (e.g. first to time event vs. recurrent event analysis), different types of testing within trials (hierarchical testing, win-ratio), interpretation of subgroup analyses
2) Novel randomized controlled trial design: registry based randomized controlled trials, adaptive, basket & umbrella & platform designs
3) Key aspects differentiating randomized controlled trials from registry-based studies
4) Systematic Reviewers and Meta-analyses of randomized controlled trials: different designs and main methods

The "Hands-on" workshops will consider:

1) Practical session on statistical methods used for clinical trials under the supervision of expert statisticians in the field

2) One among the following 3 activities:

2a) Performing a meta-analysis using STATA under the supervision of an expert statistician in the field. A trial version of STATA will be provided

2b) Critical appraisal of clinical trials and meta-analyses under the supervision of expert clinical trialists

2c) Writing a protocol for a clinical study

Forms of teaching and learning

The course will consist of:
- two and half days distance learning using the provided readings
- two days on-site lectures/workshops
- half day: exam

The formats of course activities include:
- Distance learning with critical readings of course literature
- On-site lectures/seminars
- Debates on relevant clinical trials
- Workshops
- Group work

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 the exam to pass the course.
The students who have missed course sessions will be assigned extra reading and home work to compensate for the absence.

Forms of assessment

Home-based assignment including open questions and multiple choice questions. All learning outcomes of the courses need to be achieved to pass the course.

Course literature

Recommended reading material and ppt presentations will be provided on the course platform well in advance of the course.

Other information

Replacing syllabus K2F5307 due to change of department.