



DEPARTMENT OF MOLECULAR MEDICINE AND SURGERY

K1F2980, Study Design in Clinical Research, 3 credits (hec)

Studiedesign vid klinisk forskning, 3 högskolepoäng

Third-cycle level / Forskarnivå

Approval

This syllabus was approved by the The Committee for Doctoral Education on 2023-11-13, and is valid from spring semester 2024.

Responsible department

Department of Molecular Medicine and Surgery, Faculty of Medicine

Prerequisite courses, or equivalent

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

Purpose & Intended learning outcomes

Purpose

The purpose of the course is to present an overview over study designs employed in clinical research, to explain why and how to write a study protocol, and to critically reflect on protocols' content.

The course is ideal for doctoral students that are going to conduct clinical research.

Intended learning outcomes

At the end of the course the students should be able to: 1) Independently plan and produce a study protocol, including a thorough methodological evaluation and choice of appropriate study design; 2) Critically reflect on other students' individual project work in a scientifically constructive way; 3) Interpret and critically evaluate scientific studies relevant to the course content.

Course content

1) Basic terms in epidemiology and clinical study design; 2) Measures of disease occurrence; 3) Observational studies, including cohort and case-control studies; 4) Systematic and random

errors; 5) Experimental studies, including randomised clinical trials; 6) Quality of life in clinical research; 7) Screening and diagnosis in relation to clinical research. Throughout the course the students will work on an individual project (examination 1) for peer-review (examination 2) and the students will critically review and discuss relevant scientific articles (examination 3).

Forms of teaching and learning

Lectures, individual article review, group discussions, and homework tasks. The course focuses on active learning, i.e., putting knowledge into practice and critically reflecting upon the knowledge, rather than memorising facts. Therefore, much of the focus of the course is on the individual project where students are required to develop a full study protocol including several important aspects covered in the lectures, article reviews and group discussions. Students will peer-review each other's projects during the examination.

Language of instruction

The course is given in English

Grading scale

Pass (G) /Fail (U)

Compulsory components & forms of assessment

Compulsory components

Compulsory attendance includes the scheduled lectures and seminars all held during the first week of the course. Absence will need to be replaced by individual assignments following discussion with the course co-ordinator, e.g., article reviews, with written or oral follow-up.

Forms of assessment

1) Individual project work: Develop a written comprehensive yet concise study protocol including several important aspects of study design discussed during the course; 2) Peer-review of other students' projects followed by oral presentation of their project and opposition of other students projects during the group examination; 3) Critically review scientific articles relevant to the course content and participate actively to the discussions. To pass the course the student should show that all intended learning outcomes have been reached.

Course literature

Mandatory:

Kenneth J Rothman ""Epidemiology -an introduction"" (2012) Oxford University Press, USA.
Scientific articles (handed out during course).

Recommended:

Fayers PM, Machin D. Quality of life: the assessment, analysis and reporting of patient-reported outcomes. John Wiley & Sons; 2015 Nov 23.