SK00006 Program for Doctoral Students in Clinical Research with clinical epidemiological methods, 7.5 credits

Forskarsskolan Klinisk forskning med klinisk epidemiologisk metodik, kurs 2, 7,5 högskolepoäng

Third-cycle level / Forskarnivå

Confirmation

This syllabus was confirmed by the Council for PhD Education at Sahlgrenska Academy on 2018-12-14, and was last revised on 2020-03-09. The revised course syllabus is valid from Autumn semester 2020.

Responsible Department
Institute of Clinical Sciences, Sahlgrenska Academy

Entry requirements

1. Admitted to postgraduate education.
2. To be eligible for the course the student has to be registered in third cycle at the Sahlgrenska Academy or at another faculty or university. The student also has to be admitted to Research school Clinical research employing clinical epidemiological methodology and must have passed course 1 or show documented knowledge equivalent with course 1.

The course is an elective course within the third cycle at Sahlgrenska Academy.

Learning outcomes

After completing the course the student is expected to be able to:

Knowledge and understanding

- Discuss and present arguments in support of appropriate choices of measures of incidence as well as measures of relationship based on various medical hypotheses.
- Discuss and present arguments for the choice of a study design based on various medical hypotheses.
- Interpret and critically evaluate results from studies following a clinical epidemiological

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design taking into account different types of selection bias, attrition bias and confounding bias as well as the concepts of sensitivity and specificity

- Critically examine measuring instruments with respect to sensitivity and specificity.
- Demonstrate good knowledge of methods for carrying out a data collection in a clinical study that are consistent with good ethics and Swedish law (Personal Data Act, PUL).
- Display insight into the design of instruments for acquiring information for clinical studies, quality control of the information and entering of the information in a database.
- Decide if the proposed data collection can lead to answers to determine if the hypothesized clinical effects do or do not occur.
- Display insight into the international agreements that are relevant for quality assurance of academically initiated research as well as clinical trials following the rules for “Good clinical practice” and “the CONSORT statement”.
- Display insight into quality registries and administrative registries at both the local and national level and how these may be used to address hypotheses about clinical effects.
- Display insight into different approaches to implement existing knowledge of clinical effects in clinical practice.
- Demonstrate familiarity with the manner in which a clinical study is to be registered in the approved registry (Clinical Trials Register) of a leading international clinical journal.
- Give an account of research questions, data collection and data analysis methods for problems and questions posed within the field of qualitative research methodology.

**Competence and skills**

- Independently evaluate the sources of error that may jeopardize the possibilities of drawing conclusions about clinical effects from a proposed or completed clinical study.
- Plan and put forth the details about randomized clinical trials and observational studies.
- Independently compose invitation letters providing information to participants in a clinical trial.
- Develop instruments for measuring patient focused outcome measures such as symptoms, their occurrence, intensity, duration and relevance for quality of life.
- Independently write a scientific summary of the state of knowledge for a proposed clinical effect. Display insight into the way in which authoritative organizations (“Health Technology Assessment”, “Cochrane reviews”) work to provide reviews of the state of knowledge concerning a proposed clinical effect.
- Critically examine the scientific literature with respect to research based on qualitative research methodology.

**Judgement and approach**

- Display insight into the responsibilities of the scientist toward the surrounding society.
- Maintain an ethical approach to his/her own research and the research of others and at the same time work against all scientific falsification.
- Develop a scientific approach toward all clinical practice and demonstrate ability to explain what an evidence-based clinical practice entails.

**Course content**

The course comprises three sections:
- Foundations of clinical research (clinical epidemiology), advanced level
- Study design and collection of data in a clinical study
- Good clinical practice (GCP)
- Qualitative research methods.

**Types of instruction**
Lectures, group seminars, group assignments, individual work.

**Language of instruction**
The course is given in Swedish.

The language of instruction is Swedish, if, however, the lecturer is English-speaking the language of instruction will be English. Some of the required reading will be in English.

**Grades**
The grade Pass (G) or Fail (U) is given in this course.

**Types of assessment**
Performance in the course is evaluated on the basis of written reports, examinations, and on an individual evaluation of each participant’s performance in presenting an oral report. Active participation is expected at every stage in the course.
The following is required of the student to pass the course:
- Passed written examination
- Passed oral presentation
- Passed written assignment
- One hundred percent attendance and active engagement in group seminars, group assignments as well as in lectures in GCP, HTA and quality methods.

In the case of absence due to illness or strong personal reasons, the student is to complete the course according to instructions given by the course director.

A student who has failed a test twice has the right to change examiners, if it is possible. A written application should be sent to the relevant institution.

**Course evaluation**
Evaluation of the course is achieved through the use of individually written evaluations presented anonymously along with a general discussion at the end of the course. The overall results will be communicated to the students in writing and will function as a guide for the development of the course.

**Other information**
The syllabus was confirmed by the Council for Postgraduate Studies on 2013-03-05 and was last revised on 2019-08-27 to be valid from autumn semester 2019 (Reg.nr.: U 2017/543). It was
entered into FUBAS in August 2019.