INSTITUTE OF NEUROSCIENCE AND PHYSIOLOGY

FAB820 Clinical Pharmacokinetics and Pharmacodynamics, 7.5 credits

Klinisk farmakokinetik och farmakodynamik, 7,5 högskolepoäng

Second Cycle

Confirmation

This course syllabus was confirmed by Committee for Study Programmes in Pharmacy on 2010-02-10 and was last revised on 2020-11-13 by Institute of Neuroscience and Physiology to be valid from 2020-11-13, spring semester of 2021.

Field of education: Pharmacy 100%
Department: Institute of Neuroscience and Physiology

Position in the educational system

The section for pharmacology. The course is offered as an elective course on semester 8, second cycle in the pharmacy programme, University of Gothenburg.

The course can be part of the following programme: 1) Programme in Pharmacy (F2APO)

Main field of studies	*Specialization*
Pharmaceutical Science	A1F, Second cycle, has second-cycle course/s as entry requirements

Entry requirements

For admission to the course it is required that all courses up to semester seven in the pharmacy programme has been gone through.

Learning outcomes

On completion of the course, the student is expected to independently be able to:

Knowledge and understanding

- Present pros and cons of different model- and model independent methods for analysis of pharmacokinetic or pharmacodynamic data.
- Present basic principles of non-linear regression at parameter estimation.
- Demonstrate good familiarity with the most common pharmacokinetic and pharmacodynamic structural models.
- Present the principles of population based data analysis of clinical pharmaceutical studies including statistical models of inter- and intra individual variability as well as covariate models.

Skills and ability

- Independently apply advanced knowledge in pharmacokinetics and pharmacodynamics for model independant analysis and interpretation of clinical PKPD-studies.
- Present good ability to independently, using a model-based procedure, analyse results of clinical PKPD-studies including discrimination between competing models and possible need of weighting of data.
- Complete a scientific report on data analysis of clinical studies.
- Summarise scientific literature in a delimited subject area and communicate results and own conclusions orally.

Judgement and approach

- Present a good ability to analyse and evaluate results of complex clinical studies and be able to communicate results of advanced model-based data analysis in a scientific way in the form of a written report and oral presentation.
- During the course act in a for the profession appropriate and developing way.

Course content

The course provides advanced knowledge of how absorption, tissue distribution, metabolism and secretion of drugs can be studied in clinical studies and how achieved results can be processed and interpreted. The course is based on and deepens earlier courses in pharmacokinetics/drug metabolism/pharmacodynamics, pharmacotherapy and statistics, but also pharmacology and medicinal chemistry.

Dosage recommendations for both registered and new drugs under development are based on analysis and interpretation of clinical studies. Knowledge of pharmaceutical substances' pharmacokinetic (PK) and pharmacodynamic (PD) properties forms a basis for effective and safe pharmacotherapy in different patient populations. During clinical drug development in the explorative phase, the results of studies are of considerably weight for decisions about continued development or not. Good design and analysis of studies in this respect provides a more solid knowledge base. An ongoing development in drug development is an increasing usage of modelling and simulation as aids to explore, understand, but also predict, study outcomes. The course includes analysis by

means of, for the purpose, internationally leading softwares such as WinNonlin and, to a certain extent Nonmem. The data that are analysed are authentic from clinical drug development. In addition, the course gives exercise in scientific communication.

The course is especially appropriate for individuals with an interest of future activities in drug development but also for them with interest for either pharmacotherapy or model-based analysis of biological systems.

The course includes 7.5 credits, of which data analysis with written report constitute 5 credits and presentation of advanced assignment 2.5 credits in English.

Form of teaching

Language of instruction: Swedish and English
The teaching material is mainly in English. Teaching, as well as the examination, may completely or partly be in English.

Assessment
Written presentation of data analysis and oral presentation of advanced assignment. Compulsory part with requirements of attendance is start of the course, laboratory sessions and seminars, including presentations of advanced assignments. The number of examination sessions is limited to five. Possibility to supplement failed compulsory parts can be given, at the earliest, at the next course date and only in case of a vacancy.

The student has the right to change examiner after having failed twice on the same examination, if it is practically possible. The application shall be sent to the board of the department and has to be in writing. In case the course has ceased or gone through larger changes the student should be guaranteed access to at least three examination sessions (including the regular examination session) during a time of at least a year with starting point of the earlier planning of the course.

Grades
The grading scale comprises: Pass (G) and Fail (U).

Course evaluation
Course evaluation meeting with students and course administration are held when the course is completed. Course is completed with an electronic course evaluation, which after compilation is presented to the students.

Additional information

The teaching is given as lectures, laboratory sessions, group work and seminars. The course is partly based on independent problem-solving as a form for learning.