



KURSPLAN FÖR KURS PÅ FORSKARNIVÅ

Kurskod

2625

Kursens svenska benämning

Individuell läkemedelsdosering i klinik och vid klinisk läkemedelsutveckling: tillämpning av farmakokinetiska/-dynamiska koncept

Kursens engelska benämning

Individual drug dosage in patient care and during clinical drug development: application of pharmacokinetic/-dynamic concepts

Antal högskolepoäng

4.5

Kursansvarig institution

Institutionen för laboratoriemedicin

Nivå

Forskarnivå

Särskild behörighet

Betygsskala

Godkänd/Underkänd

Kursens lärandemål

At the end of the course the student should be able to

- understand and show insights in the need to individualize drug dosage in clinical practice and during drug development based on genetic, environmental, physiological and concomitant drug therapy factors
- understand the needs for individualizing dosage regimens of drugs in clinical practice and in clinical drug development and the possibilities to design such regimens by using pharmacokinetic/dynamic theories and concepts
- design pharmacokinetic/-dynamic studies including sampling schedules for evaluation of drug concentrations and pharmacological and outcome effects to establish individualized dosage regimens to treat for example children, elderly and those with decreased liver or kidney functions or patients with infectious or cardiovascular diseases
- design individualized dosage regimens by practising modelling softwares to evaluate pharmacokinetic/dynamic parameters
- show insights in the principles for population pharmacokinetic/-dynamic modelling using sparse data sampling strategies to individualize dosage regimens
- be able to critically read, present and discuss scientific papers on individualizing dosage regimens
- be able to present and discuss own and others research projects related to clinical drug research or clinical drug development
- show documented knowledge on the needs for individualized dosage regimens and demonstrate knowledge on the principles of pharmacokinetics/dynamics to address these needs.

Kursens innehåll

BASIC LECTURES ON VARIABILITY IN DRUG RESPONSE

Genetic, environmental, age, drug-drug interaction and disease factors are reviewed and discussed focusing on clinical practice and clinical drug development. The focus will be on different pharmacotherapeutic areas and clinical situations including treatment of infectious diseases, using established and new anticoagulant drugs and achieving optimal efficacy and safety when treating children, elderly and patients with decreased kidney or liver functions.

TOOLS TO OPTIMIZE DRUG DOSAGE

The principles of therapeutic drug monitoring, drug information and of pharmacokinetics/dynamics tools are reviewed, discussed and used.

LITERATURE STUDIES ON RATIONALE FOR CURRENT DOSING REGIMENS OF SELECTED GROUPS AND

PHARMACOTHERAPEUTIC AREAS

To summarize and discuss

Studies performed to support dosing principles, Quality of studies, Available data in subgroups (males, females, children, impaired renal or hepatic function), Suggestions for supplementary studies

LITERATURE STUDIES ON INDIVIDUALIZING DOSING REGIMENS AND USING PHARMACOKINETIC/DYNAMIC TOOLS

Read, summarize, discuss and apply

INDIVIDUALIZING DOSING REGIMENS BY USING PHARMACOKINETIC CONCEPTS

Purpose of modelling, pharmacokinetic variables and their physiological correlates, model selection, compartmental vs. non-compartmental methods, population models, assessment of model performance

INDIVIDUALIZED DOSING REGIMENS BY INTEGRATION OF PHARMACOKINETIC/DYNAMIC CONCEPTS

Purpose of modelling, pharmacodynamic variables and their physiological correlates, model selection, time dimension in models, assessment of model performance

BIOSTATISTICAL TOOLS AND MATHEMATICAL CONCEPTS

Graphical presentation of data, types of data (dichotomous, categorical, continuous), logarithms and exponential functions, regression functions (linear, nonlinear, logistic), distribution fitting, parametric and nonparametric statistical tests

HANDS-ON TRAINING IN USING SOFTWARES TO DEVELOP INDIVIDUALIZED DOSING REGIMENS

Organizing the database, Graphical and statistical methods to explore data, transformation of data setting up aims of modeling, model selection, evaluation of model performance (Confidence intervals for parameters, correlations, AIC), statistical evaluation of results. The focus will be to use Win-Nonlin requiring access to own portable computer.

CLINICAL DRUG DEVELOPMENT AND DOSAGE REGIMENS

Clinical drug development to optimize dosage regimens are reviewed, discussed and applied including the procedures for registration. The focus will be on a study case of a new drug in the area of HIV/AIDS.

PRESENTATION OF OWN PROJECTS

Each course participant will shortly present and discuss own research or development project related to clinical drug research and optimizing dosage regimens in clinical practice or for development of new drugs.

Arbetsformer

Lectures, group work, PK-PD calculations, demonstrations and literature review/seminars. Except for teachers/lecturers the course will have tutors with about 5 students each.

Obligatoriska moment

Lectures, groups work, calculations, demonstrations and seminars are obligatory. If a student fail to participate in all moments it is required that the students document knowledge/understanding and document that he/she has calculated and analyzed data.

The course includes 2 weeks of full-time participation following lectures, reviewing and presenting research articles, participating in work-shops, doing practical exercises including using softwares for calculating pharmacokinetic/dynamic parameters to improve drug dosage regimens and finally presenting own research projects.

One course week is for preparatory work and for a home-examination of the course contents.

Examination

Literature reviews and home examination

Kurslitteratur och övriga läromedel

1. Principles of Clinical Pharmacology, Second Edition [Hardcover] by Arthur J. Atkinson Jr. (Editor), Darrell R. Abernethy (Editor), Charles E. Daniels (Editor), Robert Dedrick (Editor), Sanford P. Markey (Editor)

2. Malcolm Rowland, Thomas N Tozer. Clinical Pharmacokinetics and Pharmacodynamics: concepts and applications. 4th edition. Wolters Kluwer and Lippincott Williams & Wilkins, 2011

3. A First Course in Pharmacokinetics and Biopharmaceutics by David Bourne-available at <http://www.boomer.org/pkin/>

4. Prepared course material

5. Literature articles provided and recommended

Kursplan fastställd av Kurskommittén på delegation av Styrelsen för forskarutbildning på KI.

Datum för fastställande

2012-03-06

Datum för revidering

Kursansvarig

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Kontaktpersoner

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