CLINICAL PHARMACOLOGY

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Course Description

Clinical Pharmacology is the scientific discipline that involves all aspects of the relationship between drugs and humans. It is a multidisciplinary science that encompasses professionals with a wide variety of scientific skills including medicine, pharmacology, pharmacy, biomedical science and nursing. It is underpinned by the basic science of pharmacology, with added focus on the application of pharmacological principles and methods in the real world. It has a broad scope, from the discovery of new target molecules, to the effects of drug usage in whole populations.

Clinical pharmacology connects the gap between medical practice and laboratory science. The main objective is to promote the safety of prescription, maximise the drug effects and minimise the side effects. The course will focus on drug information, drug development, using PK-PD to determine optimal drug therapy, clinical drug effect assessment and other aspects of pharmacy practice related to clinical pharmacology.
Objectives

Upon completion of the course, students should be able to:
1. Use patient data and PK-PD principles to determine appropriate drug therapy and dosing.
2. Recognize and appropriately manage pharmacokinetic variability in patients with significant pharmacokinetic alterations in special populations.
3. Recognize and appropriately manage clinical pharmacogenetics, significant pharmacokinetic drug interactions and drug toxicology.
4. Perform therapeutic drug monitoring (TDM) in patients receiving drugs for which concentrations are measured in practice, and recognize physiological and laboratory markers of drug effect.
5. Recognize the preclinical development of new drugs and perform clinical trial of new drugs.

Teaching and Learning Methods

Theory: The lectures are conducted using a case-based format which promotes an active-learning environment. Other teaching styles such as didactic lectures, question-answer sessions and class discussions are used as appropriate.

Recommended Textbooks

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Course Contents

Chapter 1  Introduction to Clinical Pharmacology

1. Concept of clinical pharmacology.
2. Important history events of modern pharmacology.
4. The relationship between health, disease and drug.
5. General concept of clinical pharmacokinetics and clinical pharmacodynamics.
6. Hot spots in research of clinical pharmacology.

Chapter 2  Drug Clinical Research

1. Concept of new drugs.
2. Main contents of Good Clinical Practice (GCP).
3. Main contents and methods of phase I clinical trials.
4. Main contents and significance of phase II, III, IV clinical trials.
5. To determinate the minimum initial dose, the maximum tolerance dose of the tolerance test.
6. Bioequivalence tests and design of new drugs.
Chapter 3  Drug Registration and Administration

1. Concept of drugs, national essential drugs and over-the-counter medicines.
2. Registration classification, application and administration of drugs.
3. Selection principles of national essential drugs and over-the-counter medicines.

Chapter 4  Clinical Pharmacokinetics

1. ADME factors.
2. Review of basic pharmacokinetic parameters.
4. Dosing in liver disease and other disease states.
5. Applications of clinical pharmacokinetics.

Chapter 5  Therapeutic Drug Monitoring and Individualization of Drug Therapy

1. The history of therapeutic drug monitoring (TDM).
2. Concept of TDM.
3. The application of TDM.
4. TDM methods.
5. The methods of individualizing dosage therapy.

Chapter 6  Clinical Pharmacodynamics

1. Drug selective effects, adverse reactions.
2. Dose-effect curve, time response curve and pharmacodynamic parameters.
3. Concept of receptor, agonist, antagonist, partial agonist, receptor regulations, synergistic and antagonistic effects.
4. Concept of biomarkers.
5. Influencing factors of drug actions.

Chapter 7  Clinical Medication of Nervous System Diseases

1. Clinical medication in cerebrovascular disease.
2. Clinical medication and pathogenesis of paralysis agitans.
4. The mechanism of action of antiepileptic drug and clinical medication.

Chapter 8  Clinical Medication of Cardiovascular Diseases

1. The clinical medication of hypertension.
2. The clinical medication of angina pectoris.
3. The clinical medication of arrhythmia.
4. The clinical medication of heart failure.
5. The clinical medication of atherosclerosis.
Chapter 9  Clinical Medication of Endocrine and Metabolic Diseases

1. Indications and adverse reactions of insulin.
2. The role, action mechanism and application characteristics of oral hypoglycemic agents.
3. The main pharmacological effects and clinical medication of thyroid hormones.
4. The action mechanism, application characteristics and major adverse reactions of anti-hyperthyroid drugs.
5. The causes of osteoporosis and the clinical medication.

Chapter 10  Clinical Treatment of Digestive Diseases

1. Classification, role, application and the main adverse reactions of therapeutic drugs for ulcer.
2. Gastrointestinal motility drugs, antidiarrheal drugs, laxative drugs.
3. Drugs for treating inflammatory bowel diseases.
4. Drugs for intestinal diseases.
5. Treatment principles of drug for liver disease.
6. Drugs for protecting liver.
7. Drugs for preventing and treating hepatic encephalopathy.

Chapter 11  Drug Use in Pregnancy and Lactation Women

1. The effect of drugs on pregnant women.
   (1) Pharmacokinetics characteristics during pregnancy: absorption, distribution, metabolism and excretion.
   (2) The principles of drugs use in pregnancy, and things to notice when using drugs.
2. The effect of drugs on fetal.
   (1) Transport and metabolism of drugs in placenta.
   (2) Pharmacokinetic characteristics in fetal: absorption, distribution, metabolism and excretion.
   (3) Drugs damage to the fetus: teratogenic effects of drugs (A, B, C, D, X).
3. Drugs use in lactation women.
   (1) Transport of drugs in breast milk and the influencing factors.
   (2) The influence of drugs on lactation women and the influence of drugs on nursing infant.

Chapter 12  Drugs Use in Neonates and Kids

1. The characteristic of the pharmacokinetics and pharmacodynamics in neonates; the rational drug use in treating common diseases of neonates.
2. The principle and attention of rational drug use in neonates, infants and children.

Chapter 13  Drugs Use in Elderly Patients

1. The characteristic of the pharmacokinetics in elderly patients; the characteristic of the pharmacodynamics in elderly patients.
2. The principles of rational drugs selection and application in elderly patients.

Chapter 14 Clinical Analysis of Adverse Drug Reactions

1. Concept of adverse drug reaction (ADR).
2. Classification of ADR.
3. Concept of drug-drug interaction (DDI).
4. Mechanisms of DDI.
5. Prediction and clinical management of DDI.
6. ADR detection in clinical.

Chapter 15 Drug Abuse and Drug Dependence

2. Clinical manifestations of different types of drug dependence.
   (1) Psychological dependence.
   (2) Physical dependence.
   (3) Cross-dependence.
3. Classification and characteristics of the dependent drug:
   (1) Classification of the dependent drug.
   (2) Characteristics of the dependent drug.
4. Harm, control and prevention of drug abuse.

Chapter 16 Clinical Application of Antibacterial Drugs

1. The status quo of clinical application for antimicrobial drugs.
2. The relationship between pharmacodynamics, pharmacokinetics and the curative effect, adverse reactions.
3. The basic principles of antibacterial drugs in clinical application.
4. Therapeutic drug monitoring of antimicrobial drugs.
5. The allergic reactions of antibacterial drugs.
6. The clinical application of antibacterial drugs.

Chapter 17 Clinical Application of Antiviral Drugs

1. The classification and clinical significance of antiviral drugs.
2. The clinical application of antiviral drugs.
4. Classification and clinical application of anti-HIV drugs.

Chapter 18 Clinical Application of Anti-malignant Tumor Drugs

1. Relationship between cell proliferation kinetics and tumor chemotherapy.
2. The classification and characteristics of anti-malignant tumor drugs.
3. The clinical application of anti-malignant tumor drugs.
4. The role, development and prospect of biological therapy in the treatment of malignant tumor.
5. The principle of combination therapy.