National Training Requirements

SLOVAKIA

Specialty

Clinical Pharmacology

Klinická farmakológia

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PROJECT - STUDY PROGRAM

Specialization Study Program

in medical specialization: Clinical Pharmacology

For the health care profession: Medical Doctor

Bratislava 2015

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1. Name of the specialization study program:

Specialization study program for the specialization of **Clinical Pharmacology**.

In accordance with the Governmental Decree no. No. 111/2013, amending and supplementing the act no. 296/2010 Coll. on professional qualifications for the performance of the health care professions, the way of further education of health care workers, the system of specialized branches and the system of certified work activities as amended by the Order of the Government of the Slovak Republic No. 320/2012 coll. (hereinafter referred to as "government order").

2. Structure of the specialization study program

Compliance with the Decree of the Ministry of Health of the Slovak Republic of 5 February 2014 No. 10938-ol-2013, amending and supplementing the decree of the Ministry of Health of the Slovak Republic of 17 September 2010 No. 12422/2010-ol, laying down minimum standards for specialization study programs, minimum standards for certification study programs and minimum standards for degree programs of continuing education and their structure as amended (hereinafter referred to as "the decree").

a) Characteristics of the specialization and duration of the specialized study

1. **Clinical pharmacology** is a specialization in medicine. It is a clinical interdisciplinary specialization that applies the knowledge of experimental pharmacology in clinical disciplines to study and, by objective methods, evaluate the effect of a drug in a healthy and ill person. It belongs to clinical disciplines with wide interdisciplinary character and utilization. Its role is to integrate all relationships that ultimately relate to the clinical aspects of drug pharmacokinetics and pharmacodynamics.

2. Specialization studies last four years.

b) Determining the level of education that is a prerequisite for enrolment

Completed university doctoral study in General Medicine (MD (*Doctor of Medicine*) – in Slovak: MUDr. (*Medicinae universae doctor*).

c) The extent of theoretical knowledge, practical skills and experience needed to performance of specialized work activities

Item 1
The extent of theoretical knowledge

A. Within the common internal medicine stem
1. Aetiology, pathogenesis, clinical images, diagnosis, differential diagnosis, treatment and prevention of internal diseases,
2. Indications, contraindications, interpretation of results of diagnostic and therapeutic procedures, laboratory and auxiliary examinations in internal medicine,
3. Diagnostic and therapeutic procedures in failure of internal organs and systems (e.g. heart, lungs, kidney, liver),
4. The basics of intensive care, monitoring, diagnostic and treatment procedures in emergency medical situations,
5. Principles and practice of institutional and outpatient care for patients with internal diseases,
6. Indications and interpretation of consiliary examinations in internist's practice.

B. Within the discipline of clinical pharmacology
1. Knowledge of the clinical pharmacology of the individual medicinal drug groups and of the current medicaments belonging to them,
2. Principles and importance of basic biochemical, microbiological, and radio immunological methods for determining a medicinal drug concentration in biological materials,
3. Medicinal drugs interactions, their mechanisms and clinical relevance, as well as the practical application of this knowledge in pharmacotherapy,
4. Adverse drug reactions, diagnosis, mechanisms of onset and methods for their active and passive monitoring,
5. Basic knowledge, clinical significance and application of pharmacogenetics,
6. Pharmacokinetics of drugs under physiological and pathological conditions of the organism, with a particular focus on pharmacokinetic analysis and clinical interpretation and application of its results,
7. The pharmacodynamics of medicinal drugs, including appropriate methods for its study and evaluation under clinical conditions,
8. Principles of therapy of drug poisonings, intoxications, antidotes,
9. Principles of pharmacotherapy in pregnancy, neonatal period and childhood, and in older age,
10. The general principles of pharmacotherapy, including the adjustment of drug dosage, in the liver or kidney insufficiency or failure,
11. Principles and importance of preclinical evaluation of drugs, including the application of its results in man,
12. Methodology of the different phases of clinical trials, knowledge of methods in the first administration of a medicinal product in humans (phase I), methods in the initial clinical trials (phase II), methods in controlled clinical trials (phase III), methods in the post marketing authorization clinical trials (phase IV),
13. Legal and ethical norms in the conduct of therapeutic and non-therapeutic research in humans,
14. Principles of control and methodical guidance of rational pharmacotherapy, basics of pharmacoepidemiology,
15. Methods and procedures used in monitoring the health - economic and social aspects of pharmacotherapy in practice (pharmacoeconomics),
16. Methods of medicinal drugs consumption monitoring, analysis and forecasting,
17. Current regulations in marketing authorization procedures of medicinal products,

18. Principles and implementation of the state medicinal drug policy,
19. Drug utilization processes,
20. Theoretical and practical knowledge of information processes in clinical pharmacology, including their application within the medicinal drug – doctor – pharmacist – patient relationships,
21. Detection, documentation and elucidation of the consequences of iatrogenic drug injury, peculiarities of pharmacotherapy in geriatrics,
22. Basic knowledge and principles of medical ethics and bioethics, importance and work of ethics committees,
23. Basic theoretical and practical knowledge of the use of information technologies in clinical pharmacology,
24. Relevant legislation related to the healthcare provision.

Item 2
The extent of practical skills and experience

Section 1
Minimal number of medical procedures

A. Within the common Internal Medicine stem

Conduct of medical procedures
Standard inpatient clinical practice: patient admission, medical history, physical examination, evaluation of electrocardiogram, evaluation of x-ray scan of the chest, interpretation of auxiliary, laboratory and consulting examinations, monitoring and treatment, release: 400 patients.
Evaluation of electrocardiogram (ECG): 400
Evaluation of x-ray scans of the chest: 400
Evaluations of x-ray scan of the abdomen: 50
Venepuncture, introduction of venous coil: 50
Infusion and injection therapy: 50
Collection of arterial blood, interpretation of examinations: 20
Blood and blood products transfusion: 20
Blood coating examination: 20
Urine and urinary sediment examination: 20
Body cavity puncture: 20
Respiratory tract aspiration, inhalation therapy, ventilation: 20
Bladder catheterization in male and in female: 20
Rectoscopy: 10
Insertion of a probe into upper gastrointestinal tract: 8
Cardio-pulmo-cerebral resuscitation: 5

Assistance in medical procedures
Insertion of a central venous catheter: 5
Tracheal intubation: 5
Defibrillation, cardioversion: 5
Cardiac pacing (temporary, permanent, pacemaker, electrode replacement): 5
Echocardiography: 20
Functional examination of the cardiovascular system (e.g. 24-hour ECG monitoring (Holter), 24-hour blood pressure monitoring, ergometry, head-up tilt test: 20
Functional examination of the respiratory system: spirometry, bronchoscopy: 20

Radio diagnostics: interventional radiology, computed tomography, magnetic resonance imaging, radionuclide examination, positron emission tomography: 40
Ultrasonography: abdominal, thyroid, duplex ultrasonography of vessels: 40
Gastrointestinal endoscopy: esophagoscopy, gastroscopy, colonoscopy: 20
Organ and tissue biopsy: 10
Autopsy: 3

B. Within the discipline of clinical pharmacology
1. Practical participation in clinical trials in healthy volunteers (1 phase I study, 3 phase II – IV studies),
2. Participation in the bed-side clinical-pharmacological consultation in at least 200 hospitalized patients, in cooperation with an internal medicine department of a teaching medical hospital,
3. Participation in clinical-pharmacological care in 200 hospitalized patients,
4. Carrying out outpatient clinical-pharmacological consultations: in 200 patients as the first, admission or specialist consultation, in 200 patients as a control examination, i.e. altogether 400 outpatients in total,
5. Preparation of a clinical trial documentation according to an approved protocol in 53 subjects of a phase I-II clinical trial, and participation in the conduct of a phase III-IV clinical trial in 27 subjects (including documentation),
6. Participation in a therapeutic drug monitoring in 30 patients,
7. Participation in a pharmacoeconomic evaluation of 20 drugs or pharmacotherapeutic procedures in an inpatient medical facility or in an outpatient practice.

C. Practical experience
1. Practical mastering of organization, documentation and evaluation of clinical trials of medicinal products or medicinal drugs in all phases (I – IV),
2. Principles and practical use of non-invasive methods in study of drug pharmacodynamics in humans,
3. Practical procedure of pharmacokinetic analysis,
4. Adjustment of drug dosage in pathological conditions, including in impairment of function of parenchymal organs,
5. Knowledge of therapeutic guidelines, and of their updates,
6. Evaluation, from the point of view of the Evidence-Based Medicine (EBM), of the published information in clinical pharmacology, in related fields, or in a medical discipline, for the collaboration with which he/she prepares/specializes himself/herself,
7. Analysis and solution finding in difficult pharmacotherapeutic clinical situations in cooperation with specialists of other disciplines,
8. Work in medicinal drug commissions,
9. The use of prescriptions analysis methods, drug consumption analysis and drug consumption forecasting methods,
10. Therapeutic procedures in life or health emergencies,
11. Organizational and operational relationships of the discipline of clinical pharmacology in vertical and in horizontal levels within the structure of health care, according to the current conception of clinical pharmacology.

d) Organizational form of the specialization study
Specialization study begins with the academic year according to the study plan. It consists of a practical part and a theoretical part, while the practical training has the upper hand. It starts with the Common Internal Medicine Stem of the minimum duration of 24 months, followed by the specialization study in clinical pharmacology of the minimum duration of 24 months. The

specialization study is completed by the State Board Examination, which includes a defence of a written paper.

e) The scope and focus of professional health care practice performed at individual workplaces of health facilities, its minimum length and time course

A. Common Internal Medicine Stem of 24 months
1. Standard internal medicine department: 12 months
2. Intensive care unit: 2 months
3. Admissions internal medicine department's office or an emergency admissions department of a general hospital: 1 month
4. Optional Internal Medicine Specialty (e.g. Internal Medicine, Gastroenterology, Geriatrics, Pneumology and Phthisiology, Occupational Medicine): 2 months
5. Department of Infectious Diseases (including the basics of clinical microbiology and parasitology): 1 month
6. Department of Clinical Oncology: 1 month
7. Department of Laboratory Medicine: 1 month (or 15 days in the laboratory of haematology and transfusiology and 15 days in the laboratory of clinical biochemistry)
8. Department of Surgery: 2 months
9. Department of Neurology: 1 month
10. Department of Anaesthesiology and Intensive Medicine: 1 month.

B. Clinical Pharmacology in the duration of 24 months, of which:
1. Department of Clinical Pharmacology: 12 months
2. Clinical Pharmacology Outpatient Clinic or Office: 7 months
3. Department of Experimental Pharmacology: 3 months
4. Department of Toxicology: 1 month
5. State Institute for Drug Control: 1 month

Translation from the Slovak original: Prof. Jozef Glasa, MD, PhD.[2], President, Slovak Society of Clinical Pharmacology, b. Slovak Medical Association

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