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mous Educational Institution of Higher Education FRIENDSHIP UNIVERSITY OF RUSSIA RUDN University

Institute of Medicine

educational division (faculty/institute/academy) as higher education programme developer

COURSE SYLLABUS

Clinical Pharmacology

course title

Recommended by the Didactic Council for the Education Field of:

31.05.01 General Medicine

field of studies / speciality code and title

The course instruction is implemented within the professional education programme of higher education:

General Medicine

higher education programme profile/specialisation title

2022-2023

1. COURSE GOAL(s)

The goal of the course "Clinical Pharmacology" is toequip students with theoretical knowledge and practical skills of choosing and prescribing effective, safe and economically reasonable drugs in order to be able to use rational and personalized pharmacotherapy based on the authentic data on pharmacokinetics, pharmacodynamics, drug interactions, adverse drug reactions, pharmacogenetics, pharmacoeconomics, pharmacoepidemiology and principles of evidence-based medicine.

2. REQUIREMENTS FOR LEARNING OUTCOMES

Mastering the course (module) "Clinical Pharmacology" is aimed at the development of the following competences /competences in part: General Professional Competence (GPC)-7, Professional Competence (PC)-3.

Competence code	Competence descriptor	Competence formation indicators (within this course)	
GPC-7	Being able to prescribe treatment and monitor its efficacy and safety.	GPC-7.1. Having skills of general clinical examination, assessment of laboratory and instrumental diagnostic test results.	
PC-3	Being able to prescribe treatment	PC-3.1. Developing the treatment plan for a disease or condition with regards to diagnosis, age and clinical picture in compliance with relevant clinical practice guidelines.	
rC-3	and monitor its efficacy and safety.	PC-3.2 Prescribing medications, medical device	

Table 2.1. List of competences that students acquire through the course study

3. COURSE IN HIGHER EDUCATION PROGRAMME STRUCTURE

The course refers to the <u>core</u>/variable/elective* component of (B1) block of the higher educational programme curriculum.

* - Underline whatever applicable.

Within the higher education programme students also master other (modules) and / or internships that contribute to the achievement of the expected learning outcomes as results of the course study.

Table 3.1. The list of the higher education programme components/disciplines that contribute to the achievement of the expected learning outcomes as the course study results

Previous courses/modules*	Competence code	Competence descriptor	Previous courses/modules*	Subsequent courses/modules*
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GPC-7	Being able to prescribe treatment and monitor its efficacy and safety.	Pharmacology; Biotechnology; Medical recovery; Dermatovenerology; Neurology, medical genetics, neurosurgery; Professional diseases; Faculty surgery; Endocrinology; Polyclinical therapy; Urology; Obstetrics and gynecology; General surgery; Traumatology, orthopedy; Pediatrics; Evidence-based medicine; Tracheotomy in modern otolaryngology; Out-patient cardiology; Assistant of ward nurse; Assistant of physician; Assistant of physician in out-patient primary care	Anesthesiology, resuscitation, intensive care; Maxillofacial surgery; Endoscopic urology; Reproductive health; Oncology, x-ray therapy; Hospital therapy
PC-3	Being able to prescribe treatment and monitor its efficacy and safety.	Medical recovery; Dermatovenerology; Neurology, medical genetics, neurosurgery; Propedeutics of internal diseases; Imaging diagnostics; Professional diseases; Faculty surgery; General surgery; Faculty surgery; Urology; Ophthalmology; Life safety; Dentistry; Obstetrics and gynecology; Pediatrics; Evidence- based medicine; Actual issues of neonatology; Fundamentals of child threpsology; Out-patient cardiology; Assistant of physician; Assistant of physician in out-patient primary care	Anesthesiology, resuscitation, intensive care; Disaster medicine; Oncology, radiation therapy; Hospital therapy; Hospital surgery; Pediatric surgery

* To be filled in according to the competence matrix of the higher education programme.

4. COURSE WORKLOAD AND ACADEMIC ACTIVITIES

The total workload of the course <u>"Clinical Pharmacology"</u> is 3 credits (108 academic hours).

Table 4.1. Types of academic activities during the periods of higher education programme mastering (*full-time training*)*

Types of academic activities	TOTAL, academic hours	Semesters
Types of academic activities	(ac.h)	11
Classroom learning, <i>ac.h</i> .	54	54
Including:		
Lectures (LC)	-	-
Lab work (LW)	-	-
Seminars (workshops/tutorials) (S)	54	54

Types of academic activities		TOTAL, academic hours	Semesters
		(ac.h)	11
Self-studies 54		54	54
Evaluation and assessment			
(exam/passing/failing grade)			
Course workload	academic	108	108
	hours_	100	100
	credits	3	3

* To be filled in according to the competence matrix of the higher education programme.

5. THE COURSE MODULES AND CONTENTS

Course module title	Course module contents (topics)	Academic activities types
	 Topic 1.1. Subject and tasks of clinical pharmacology (CP). Clinical research. Principles of evidence-based medicine. Subject and tasks of CP. Pharmacoepidemiology, pharmacoeconomics, their content and significance. Phases of clinical research of novel drugs, modern approaches to drug development. Concepts of controlled clinical trials, principles of evidence-based medicine. Topic 1.2. Fundamentals of clinical 	S, S-s
Module 1 General issues of clinical pharmacology	pharmacodynamics. Clinical pharmacodynamics. Basic concepts. The difference between drugs in pharmacological action. Pharmacological and pharmacodynamic "targets". Pharmacodynamic and clinical efficacy of drugs. Criteria for assessing pharmacodynamic and clinical efficacy.	5, 5-5
	Topic 1.3. Fundamentals of clinical pharmacokinetics. Subject and tasks of clinical pharmacokinetics. Pharmacokinetic studies in clinical pharmacology. Pharmacokinetic curve. Types of pharmacokinetic curve. Control over the concentration of drugs in clinical practice (Therapeutic Drug Monitoring), its purpose. The main pharmacokinetic parameters, their role in rational pharmacotherapy. Patient factors influencing bioavailability,	S, S-s

Table 5.1. The content of the discipline and types of academic activities

Course module title	Course module contents (topics)	Academic activities types
	distribution, metabolism and excretion of	
	drugs. Principles of dosing drugs.	
	Topic 1.4. Interaction of drugs. The concept	S, S-s
	of interaction of drugs, types of interaction	
	(pharmacokinetic, pharmacodynamic). Results	
	of drug interaction. Principles of rational	
	combination of drugs.	
	Topic 1.5. Drug safety. Adverse drug	S, S-s
	reactions. Modern concepts and terms in the	
	field of drug safety. Methods of detection,	
	forecasting, prevention and correction of	
	ADRs. Prescription of drugs to pregnant and	
	breast-feeding women, classification of risk. General principles of increasing the safety of	
	pharmacotherapy in elderly patients.	
	Fundamentals of Pharmacovigilance. Topic 1.6. Fundamentals of rational	S, S-s
	pharmacotherapy (P-method). General	5, 5-5
	principles of evaluating the effectiveness and	
	safety of the use of drugs in patients,	
	including the assessment of quality of life.	
	The importance of clinical and laboratory-	
	instrumental methods for assessing the	
	effectiveness and safety of drug use.	
	Methodological bases of rational choice of	
	appropriate drugs. Selection of medicines for	
	compiling an individual list of P(personal)-	
	drugs. The process of rational individualized	
	treatment (P-treatment).	
	Topic 2.1. Clinical pharmacology of drugs	S, S-s
	affecting the main functions of the	
	myocardium. Clinical pharmacology of	
	medications for treatment of stable ischemic	
	heart disease and chronic heart failure.	
	Clinical pharmacology of antiarrhythmic	
Module 2 Specific issues	drugs. Principles of clinical and	
of clinical	pharmacological approach to the choice of	
pharmacology	medicines for the treatment of these diseases	
	and relief of emergency conditions in the	
	pathologies of the cardiovascular system.	S, S-s
	Topic 2.2. Clinical pharmacology of drugs	6-6,6
	affecting vascular tone. Clinical pharmacology of medications for treatment of	
	stable ischemic heart disease and chronic	
	heart failure. Clinical pharmacology of	

Course module title	Course module contents (topics)	Academic activities types
	antiarrhythmic drugs. Principles of clinical	
	and pharmacological approach to the choice	
	of medicines for the treatment of these	
	diseases and relief of emergency conditions in	
	the pathologies of the cardiovascular system.	
	Topic 2.3. Clinical pharmacology of lipid-	S, S-s
	lowering agents and metabolic correctors.	
	Methods of diagnostics and types of	
	dyslipidemias. Selection of optimal drugs	
	depending on the type of hyperlipidemia.	
	Methods for evaluating efficiency and safety.	
	Diagnosis, correction and prevention of	
	adverse reactions. Possible interactions in	
	combination with drugs of other groups.	
	Topic 2.4. Clinical pharmacology of drugs	S, S-s
	affecting hemostasis and hemopoesis. Clinical	
	pharmacology of drugs for the treatment and	
	prevention of arterial and venous thrombosis.	
	Clinical Pharmacology of medications to stop	
	and preventing bleeding. Clinical	
	pharmacology of drugs for the treatment of	
	anemia. Principles of choice of appropriate	
	agents and their dosage regimen depending on	
	the state of coagulation, anticlotting,	
	fibrinolytic systems of the patient. Methods	
	for evaluating the effectiveness and safety of	
	the treatment.	
	Topic 2.5. Clinical pharmacology of	S, S-s
	medications affecting the respiratory system.	5,55
	Clinical pharmacology of anti-asthmatic	
	drugs; medications for the treatment of COPD	
	and pulmonary hypertension. Principles of	
	clinical and pharmacological approach to the	
	choice of drugs for the treatment of these	
	diseases. Control over the effectiveness and	
	safety of the treatment. Rational drug	
	combinations.	
	Topic 2.6. Clinical pharmacology of	S, S-s
	medications affecting the digestive system.	
	Clinical pharmacology of drugs for the	
	treatment of gastric and duodenal ulcer,	
	gastroesophageal reflux disease (GERD).	
	Clinical pharmacology of drugs for the	
	treatment of acute and chronic hepatitis;	
	diseases of the biliary tract; pancreatic	

Course module title	Course module contents (topics)	Academic activities types
	diseases; bowel diseases. Principles of clinical	
	and pharmacological approach to the choice	
	of medicines for the treatment of these	
	diseases. Control over the effectiveness and	
	safety of the treatment. Rational drug	
	combinations.	
	Topic 2.7. Clinical pharmacology of	S, S-s
	medications used in diseases of the kidneys	,
	and urinary tract. Clinical pharmacology of	
	medicines used for the treatment of	
	glomerulonephritis, pyelonephritis, renal	
	failure, urinary tract and bladder diseases.	
	Topic 2.8. Clinical pharmacology of	S, S-s
	medicines used in endocrinology. Clinical	··· · · · ·
	pharmacology of hypothalamus hormones and	
	their synthetic analogues; pituitary hormones	
	and their synthetic analogues; adrenal cortex	
	hormones and their synthetic analogues; sex	
	hormones and their synthetic analogues.	
	Contraceptives and anti-menopausal agents.	
	Clinical pharmacology of medicines affecting	
	thyroid function and glucose-lowering drugs.	
	Topic 2.9. Clinical pharmacology of drugs for	S, S-s
	the treatment of inflammatory diseases of	,
	connective tissue. Clinical pharmacology of	
	NSAIDs; GCSs; monoclonal antibodies.	
	Topic 2.10. Clinical pharmacology of	S, S-s
	medicines used for immune systems	
	pathologies and allergic conditions. Clinical	
	pharmacology of cytostatics,	
	immunomodulators and anti-allergic drugs.	
	Topic 2.11. Clinical pharmacology of anti-	S, S-s
	infectious drugs. Clinical pharmacology of	,
	antibacterial drugs; medications for the	
	treatment of antibiotic-associated diarrhea;	
	antiviral drugs; anti-mycotics.	
	Topic 2.12. Clinical pharmacology of	S, S-s
	psychotics. Neuroleptics; Tranquilizers;	
	Antidepressants; Sleeping pills; Nootropic	
	drugs. Clinical and pharmacological	
	approaches to the selection of groups and	
	specific drugs for pharmacotherapy of basic	
	psychopathological syndromes.	
*	or full -time training: LC - lectures: LW - lab work: S - seminar	1

* - to be filled in only for <u>full</u>-time training: LC - lectures; LW - lab work; S - seminars.

6. CLASSROOM EQUIPMENT AND TECHNOLOGY SUPPORT REQUIREMENTS

Type of academic activities	Classroom equipment	Specialised educational / laboratory equipment, software, and materials for course study (if necessary)
Lab work	Classroom for lab work, individual and group consultations, ongoing control and interim attestation, self- studies equipped with a set of specialized furniture, whiteboard; interactive system SMART.	technical equipment: interactive board SMART with multimedia projector SMART, laptop HP with stable Internet connection. Software: Microsoft Windows, MS Office 365, MS Teams, Chrome (latest stable release), TUIS system
Self-studies	Classroom for lab work, individual and group consultations, ongoing control and interim attestation, self- studies equipped with a set of specialized furniture, whiteboard	technical equipment: multimedia projector BENQ, laptop HP. Software: Microsoft Windows, MS Office 365, MS Teams, Chrome (latest stable release), TUIS system

Table 6.1. Classroom equipment and technology support requirements

* The premises for students' self-studies are subject to MANDATORY mention

7. RESOURCES RECOMMENDED FOR COURSE STUDY

Main readings:

1. Clinical Pharmacology / P.N. Bennett, M.J. Brown. - 10th ed.; Книга на английском языке. - Edinburgh: Churchill Livingstone, 2008. - 694 p.: il. - ISBN 978-0-443-10245-5: 2048.65

Additional readings:

1. Basic and Clinical Pharmacology / В. Katzung, S. Masters. - 11th ed.; Книга на английском языке. - New York: McGraw-Hill, 2009. - 1218 p.: il. - (LANGE Basic Science). - ISBN 978-007-127118-9: 4318.03.

2. S.B. Fitilev, I.I. Shkrebneva, A.V. Vozzhaev. The Fundamentals of Rational Pharmacotherapy (Problem-Based Method of Teaching Clinical Pharmacology or How to Create Your Own Guideline) (учебное пособие на английском языке). Москва: РУДН, 2017. – 85 с.

Internet (based) sources

1. Electronic Library System (ELS) of the RUDN University and third-party ELS, to which university students have access on the basis of concluded contracts:

- Electronic Library System (ELS) of the RUDN<u>http://lib.rudn.ru/MegaPro/Web</u>
- ELS «Университетская библиотека онлайн» <u>http://www.biblioclub.ru</u>
- ELS Юрайт <u>http://www.biblio-online.ru</u>
- ELS «Консультант студента» <u>www.studentlibrary.ru</u>
- <u>ScienceDirect https://www.sciencedirect.com/</u>
- <u>Springer https://www.springer.com/gp</u>
- Oxford University Press http://global.oup.com/?cc=ru
- 2. Databases and search engines:
 - State register of drugs <u>http://www.drugreg.ru/Bases/WebReestrQuery.asp</u>
 - Source on pharmacogenetics <u>http://www.pharmgkb.org/</u>
 - Source of drug interactions <u>http://medicine.iupui.edu/flockhart/</u>

Learning toolkits for self-studies during the development of the discipline

Methodological guidelines for the implementation and execution of control and independent work on the discipline «Clinical pharmacology».

* - All teaching materials for self-studying of students are placed in accordance with the current procedure on the discipline page in the RUDN LMS TUIS.

Training toolkit for self- studies to master the course *:

1. The set of lectures on the course "Clinical Pharmacology"

* The training toolkit for self- studies to master the course is placed on the course page in the university telecommunication training and information system under the set procedure.

8. ASSESSMENT TOOLKIT AND GRADING SYSTEM* FOR EVALUATION OF STUDENTS' COMPETENCES LEVEL UPON COURSE COMPLETION

The assessment toolkit and the grading system* to evaluate the competences formation level (GPC-7,PC-3) upon the course study completion are specified in the Appendix to the course syllabus.

* The assessment toolkit and the grading system are formed on the basis of the requirements of the relevant local normative act of RUDN University (regulations / order).

DEVELOPERS:

Professor of the Department of General and Clinical Pharmacology

S.B. Fitilev

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