

Federal State Autonomic Educational Institution of Higher Education
«Peoples' Friendship University of Russia»

Medical Institute

Recommended MCSD

ACADEMIC COURSE WORKING PROGRAM

Course name

Clinical Pharmacology

Recommended for the direction of training (specialty)

31.05.03 Dentistry

Program (profile, specialization)

Dentistry

1. Aims and objectives of discipline: To master 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.

Objectives:

- gain knowledge of general issues of clinical pharmacology with rationale of its meaning in choosing drugs that are used in dental practice;
- gain skills necessary in dentist’s work to prescribe personalized pharmacotherapy to patients through choosing effective and safe drugs and to use adequate methods of monitoring safety and efficacy of prescribed medical treatment;
- gain skills necessary in dentist’s work to use personalized systemic and local pharmacotherapy in patients with pathology of maxillofacial area and oral cavity.
- gain skills of implementing knowledge of PK and PD properties of main groups of drugs in treating patients with urgent conditions in dental practice;
- gain basic knowledge of clinical pharmacology methods that define rational prescribing (assessment of efficacy and safety, drug formular, regional antibiotic resistance status, cost/efficacy ratio, pharmacoepidemiology studies).

2. Place of discipline in the structure of OP HE:

Discipline «*Clinical Pharmacology*» refers to the basic part of Block 1 of the curriculum.

Table 1 contains preceding and following disciplines aimed at forming competence discipline in accordance with the matrix competences OP HE.

Table 1. Preceding and following disciplines aimed at creating competencies.

№	Code and title of competence	Preceding disciplines	Following disciplines (groups of disciplines)
General Professional Competences			
1.	GPC-6. Being able to prescribe non-drug and drug treatment, monitor its efficacy and safety when solving professional tasks	Pharmacology; Internal diseases; General surgery; Surgical diseases; Imaging diagnostics; Psychiatry and narcology; Otolaryngology; Propedeutics; Cariesology and diseases of hard tissues of teeth; Endodontics; Gerodontistry and diseases of the mucous membranes of the oral cavity; Periodontics; Local anesthesia and anesthesiology in dentistry; Surgery of oral cavity; Diseases of head and neck; Ethics, law and management in dentistry	Oral and gnatic surgery; Implantology and reconstructive surgery of oral cavity; Introduction to medical elementology; Physiotherapy of dental disorders and dental maintenance of cancer patients
Professional Competences (professional task types: medical)			
2.	PC-2. Being able to prescribe, monitor the efficacy and safety of non-drug and drug treatment	Internal diseases; Imaging diagnostics; Dermatovenerology; Neurology; Obstetrics; Pediatrics; Prevention and community dentistry; Cariesology and diseases of hard tissues of teeth; Endodontics; Gerodontistry and diseases of the mucous membranes of the oral cavity; Periodontics; Pediatric dentistry; Clinical dentistry; Gnatology and functional diagnostics of temporal mandibular joint; Assistant of dentist (surgeon); Assistant of dentist (therapist); Assistant of dentist (orthopedist); Assistant of dentist (pediatrics)	Prosthodontics (simple); Prosthodontics in cases of total absence of teeth; Prosthodontics of tooth rows (complicated); Pediatric oral surgery; Orthodontics and pediatric prosthodontics; Cancer dentistry and radiation therapy; Oral prosthodontics; Assistant of general practitioner

3. Requirements to the results of mastering the discipline: The process of studying the discipline is aimed at the formation of the following competences:

Competences	Competence name	Competence achievement indicators
GPC-6.	Being able to prescribe non-drug and drug treatment, monitor its efficacy and safety when solving professional tasks	GPC-6.1. Developing a plan for dental disease treatment taking into account the diagnosis, age and clinical picture in accordance with the current procedures for the provision of medical care, clinical guidelines (treatment protocols) on the provision of medical care taking into account the medical care standards.
		GPC-6.3. Assessing the possible side effects of taking medicinal drugs.
		GPC-6.5. Organizing the prevention and treatment of complications, side effects, undesirable reactions, including the unforeseen ones, which can arise from diagnostic or medicinal manipulations, use of drugs and (or) medical devices, non-drug treatment at a dental appointment.
		GPC-6.7. Prescribing medicinal drugs, medical devices, taking into account the diagnosis, age and clinical picture, and in accordance with the current procedures for the provision of medical care, clinical guidelines (treatment protocols) on the provision of medical care taking into account medical care standards.
		GPC-6.9. Evaluating the efficacy and safety of using medicinal drugs, medical devices and other methods of treatment at a dental appointment.
PC-2.	Being able to prescribe, monitor the efficacy and safety of non-drug and drug treatment	PC-2.2. Selecting drugs and medical devices (including dental materials) for dental disease treatment assessing the possible side effects of taking medicinal drugs.
		PC-2.4. Selecting the type of local anesthesia/anesthesia and assessing the possible complications caused by using it.

As a result of study of the discipline a student must:

Know:

1. Key principals of treatment of most widely spread diseases and conditions.
2. Pharmacological groups applied to provide medical care in treatment of most widely spread diseases and conditions; its' mechanisms of action, PK peculiarities in risk groups; indications and contraindications.
3. Compatibility of main drugs, possible complications, adverse reactions (including serious and unexpected), approaches to manage urgent conditions.

Have skills to:

1. Develop treatment plan of children, adults, elderly and pregnant women with most widely spread diseases and conditions in compliance with standards and guidelines of medical care.
2. Predict and prevent complications and adverse reactions (including serious and unexpected) caused by drugs.

Manage:

1. Prescription of drugs to treat dental conditions in different categories of patients (pregnant, children, adults, elderly) in compliance with clinical practice guidelines.
2. Development of optimal management approaches to treat dental pathology in terms of concomitant general somatic diseases.
3. Assessment of efficacy and safety of prescribed treatment.
4. Choosing the way of administration and dosage regimen of medications.
5. Writing recipes in diseases, pathological conditions.
6. Informing and instructing patients when prescribing pharmacological treatment.
7. Pharmacotherapy of urgent conditions.

4. Volume of discipline and types of study:

General credit value of the discipline is **2 credit units**.

Type of study	Total hours	Semesters
		10
Class hours (total)	45	45
Including:	-	-
<i>Laboratory training (LT)</i>	45	45
Self-work (total)	27	27
Total labor input	Hours	72
	Credit Units	2

5. Contents of the discipline.

5.1. The contents of the discipline sections:

№	Name of the discipline section	Contents of the section
1.	General issues of clinical pharmacology.	
	1.1. Subject and tasks of clinical pharmacology (CP). Clinical research. Principles of evidence-based medicine.	Subject and tasks of the CP. Pharmacoepidemiology, pharmacoconomics, their content and significance. Federal Law on Medicines. Stages of clinical trials of new drugs, modern methods of clinical trials. Concepts about controlled clinical trials, principles of evidence-based medicine, its main provisions.
	1.2. Fundamentals of clinical pharmacokinetics.	Subject and tasks of clinical pharmacokinetics. Pharmacokinetic studies in clinical pharmacology. Bioequivalence studies. 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 (equilibrium concentration, time required to achieve it; minimum equilibrium concentration; maximum equilibrium concentration; maximum concentration (C _{max}); time to reach maximum concentration (T _{max}); half-life period (T _{1/2}); average retention time of the drug in the body (MRT); area under the pharmacokinetic curve (AUC). Patient factors influencing bioavailability, distribution, metabolism and excretion of drugs. Principles of dosing drugs. Dosing as a way

		to influence the concentration-time curve. Types of doses. Correction of the dose in case of violations of the function of organs of removal of drugs.
	1.3. Fundamentals of clinical pharmacodynamics.	Clinical pharmacodynamics. Definition. Basic concepts. The difference between drugs in pharmacological action. Pharmacological and pharmacodynamic “targets”. The main approaches to achieving the “target” – selective action of drugs. Drug effects. Pharmacodynamic and clinical efficacy of drugs. Criteria for assessing pharmacodynamic and clinical efficacy of drugs.
	1.4. Interaction of drugs.	The concept of interaction of drugs, types of interaction (pharmacokinetic, pharmacodynamic). Results of drug interaction. Principles of rational combination of drugs.
	1.5. Drug safety. Adverse drug reactions.	Modern concepts and terms in the field of drug safety (adverse effect (AE), adverse drug reactions (ADR), classification of risk levels and types of ADR (WHO). Evaluation of the probability of the relationship of an undesirable event with the action of the drug. Methods of detection, forecasting, prevention and correction of ADR. Features of drug use by pregnant women, classification of risk levels. The use of drugs during lactation. General principles of increasing the safety of pharmacotherapy in elderly patients. Organization of drug safety control systems in different countries. Pharmacovigilance.
2.	Clinical and pharmacological approaches to the choice and use of medications in dental diseases and emergency conditions.	
	2.1. Clinical and pharmacological approaches to the choice and use of antibacterial drugs in dental practice.	Clinical pharmacology of antibiotics. Clinical pharmacology of synthetic antimicrobial agents. Principles of rational anti-infection therapy. Targeted and empirical therapy of maxillo-face infections. Assignment of drugs in risk groups. Informing and instructing patients about the rules of administration of drugs. Monitoring the effectiveness and safety of the treatment. Rational combinations.
	2.2. Clinical and pharmacological approaches to the choice and use of antifungal and antiviral drugs in dental practice.	Clinical pharmacology of antimycotic drugs. Clinical pharmacology of antiviral drugs. Assignment of drugs in risk groups. Informing and instructing patients about the rules of administration of drugs. Monitoring the effectiveness and safety of the treatment.
	2.3. Clinical and pharmacological approaches to the choice and application of antiseptics and irrigants in dental practice.	Clinical pharmacology of antiseptics. Frequency and features of application in the treatment of odontogenic and neodontogenic infections. Features of the use of antiseptics in patients at risk (pregnant, lactating women, children, comorbidities). Rational and irrational combinations of antiseptics. Clinical pharmacology of irrigation agents and chelate agents. Compatibility of solutions during irrigation. The main provisions justifying the need for disinfection of root canals.
	2.4. Clinical and pharmacological approaches to the choice and application of painkillers in dental practice	Clinical pharmacology of local anesthetics. Preventive measures and control of the safety of the use of LA. Interaction of local anesthetics with drugs of other pharmacological groups. Selection of a specific anesthetic (and vasoconstrictor) for standard dental procedures, as well as in patients with comorbidities, pregnant and lactating women, children, elderly persons of age. Clinical pharmacology of non-arctic analgesics Clinical pharmacology of narcotic analgesics Clinical pharmacology of coanalgesics. Basic principles of diagnosis and treatment of acute and chronic pain syndrome. Evaluation of the effectiveness of anesthesia. Features of

		analgesia of oncological pains 1-3-degree intensity (WHO). Analgesia in risk groups.
2.5. Clinical and pharmacological approaches to the choice and use of anti-inflammatory, anti-allergic drugs and immunomodulators.		Clinical pharmacology of NSAIDs. General principles of appointment and dosing of NSAIDs, control measures for long-term use of NSAIDs, risk factors of the main NSAIDs. Drug interactions. Clinical pharmacology of corticosteroids. Methods for assessing the effectiveness and safety of pharmacotherapy with glucocorticoids. Diagnosis, correction and prevention of unwanted reactions. Possible interactions in combination with drugs of other groups. Clinical pharmacology of anti-allergic drugs. Principles of selection of drugs in the treatment of allergies of immediate type. Methods for evaluating efficiency and safety. Possible interactions in combination with drugs of other groups.
2.6. Clinical and pharmacological approaches to the choice and use of medicines used in hemostasis disorders (bleeding and thrombosis).		Clinical pharmacology of antiplatelets, anticoagulants and fibrinolytics. Features of the use of agents inhibiting the hemostasis system (principles of treatment and prevention of arterial and venous thrombosis), laboratory monitoring of the effectiveness and safety of the drug used s, overdose treatment. Tactics of management of patients in dental interventions. Clinical Pharmacology of hemostatics. Principles of treatment and prevention of acute and chronic bleeding. Stopping bleeding associated with systemic pathology (cirrhosis, portal hypertension, hemophilia). Rational use of existing medicinal forms of drugs in the practice of a dentist.
2.7. Clinical pharmacology of drugs for the treatment of phosphorus-calcium metabolism disorders.		Clinical pharmacology of calcium and phosphorus preparations, vitamin D preparations and its metabolites, calcitonin, bisphosphonates, reproductive hormones (estrogens), fluorine preparations, other medicinal products agents affecting the metabolism of calcium and phosphorus.
2.8. Clinical and pharmacological approaches to the choice and use of medicines used in urgent and life-threatening conditions.		Principles of diagnosis and selection of drugs in the treatment of the following emergency conditions: anaphylactic shock, hypertensive crisis, angina attack, acute heart failure, paroxysm of supraventricular tachycardia, paroxysm of flickering arrhythmia, paroxysm of ventricular tachycardia and, Morgania-Adams-Stokes attack, pulmonary embolism, bronchial asthma attack, gastrointestinal bleeding, keto-acidic coma, hypoglycemic coma, convulsive syndrome, poisoning with opiates.

5.2. Sections of disciplines and types of classes:

№	Name of the section of discipline	LT	SW	Total hours
1.	Subject and tasks of clinical pharmacology (CP). Clinical research. Principles of evidence-based medicine.	0,5	-	0,5
2.	Fundamentals of clinical pharmacokinetics.	3,5	1,0	4,5
3.	Fundamentals of clinical pharmacodynamics.	1,0	-	1,0
4.	Interaction of drugs.	3,0	1,0	4,0
5.	Drug safety. Adverse drug reactions.	3,0	1,0	4,0
6.	Clinical and pharmacological approaches to the choice and use of antibacterial drugs in dental practice.	6,0	2,0	8,0
7.	Clinical and pharmacological approaches to the choice and use of antifungal and antiviral drugs in dental practice.	3,5	0,5	4,0

8.	Clinical and pharmacological approaches to the choice and application of antiseptics and irrigants in dental practice.	2,0	0,5	2,5
9.	Clinical and pharmacological approaches to the choice and application of painkillers in dental practice	6,0	1,0	7,0
10.	Clinical and pharmacological approaches to the choice and use of anti-inflammatory, anti-allergic drugs and immunomodulators.	5,5	0,5	6,0
11.	Clinical and pharmacological approaches to the choice and use of medicines used in hemostasis disorders (bleeding and thrombosis).	5,5	0,5	6,0
12.	Clinical pharmacology of drugs for the treatment of phosphorus-calcium metabolism disorders.	-	2,0	2,0
13.	Clinical and pharmacological approaches to the choice and use of medicines used in urgent and life-threatening conditions.	5,5	2,0	7,5
14.	Coursework (term paper)	-	15,0	15,0
TOTAL HOURS:		45	27	72

6. Laboratory practice

№	№ discipline section	Topics of laboratory training	Workload (hours)
1.	1.1., 1.2., 1.3., 1.5.	Introduction to clinical pharmacology. Principles of clinical pharmacodynamics and clinical pharmacokinetics. Drug safety, adverse drug reactions.	5,5
2.	1.2., 1.4.	Principles of drug administration and dosing. Drug interactions. Fundamentals of clinical pharmacogenetics.	5,5
3.	2.4	Clinical pharmacology of local anesthetics.	6,0
4.	2.4., 2.5.	Clinical pharmacology of analgesics. Pharmacotherapy of acute and chronic pain. Clinical pharmacology of anti-inflammatory and anti-allergic drugs.	5,5
5.	2.1.	Principles of rational antimicrobial and anti-infective pharmacotherapy.	6,0
6.	2.1, 2.3.	Guidelines of treatment of diseases caused by bacterial, viral and fungal agents in dental practice. Antiseptics.	5,5
7.	2.6., 2.7.	Clinical pharmacology of drugs affecting hemostasis. Drugs to treat phosphoric calcium metabolism disorders	5,5
8.	2.8.	Urgent pharmacology care in dental practice.	5,5
9.	1-2	Final test / Defense of coursework (term paper) CREDIT	

7. Laboratory training: *not applicable*

8. Material and technical support of the discipline:

Number of clinical bases – 2

Number of premises given to the department – 4

Number of units of educational and scientific equipment – 6

Room	Room name	Equipment
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121 (133)	Conference hall (ГБУЗ ГП № 2 ДЗМ) – classroom for lectures.	Multimedia device.
400	Training class (ГБУЗ ГП № 2 ДЗМ) – classroom for seminars, group and individual consultations, ongoing control and interim attestation, as well as for independent work.	Multimedia device, interactive board SMART. Internet access.
301	ГБУЗ ГКБ № 24 ДЗМ 3rd floor – classroom for seminars, group and individual consultations, ongoing control and interim attestation, as well as for independent work. <i>2nd floor</i> – classroom for lectures.	Multimedia device, board. Internet access.

9. Information support of the discipline:

a) Software:

- MS Office;
- Internet Explorer;
- SMART NoteBook.

б) Databases, reference and search systems:

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 <http://lib.rudn.ru/MegaPro/Web>
- ELS «Университетская библиотека онлайн» <http://www.biblioclub.ru>
- ELS Юрайт <http://www.biblio-online.ru>
- ELS «Консультант студента» www.studentlibrary.ru
- ScienceDirect <https://www.sciencedirect.com/>
- Springer <https://www.springer.com/gp>
- Oxford University Press <http://global.oup.com/?cc=ru>

2. Databases and search engines:

- State register of drugs <http://www.drugreg.ru/Bases/WebReestrQuery.asp>
- Source on pharmacogenetics <http://www.pharmgkb.org/>
- Source of drug interactions <http://medicine.iupui.edu/flockhart/>

10. Educational and methodical support of the discipline.

a) Main literature:

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

b) Additional literature:

1. Basic and Clinical Pharmacology / B. 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.

11. Guidelines for students on the development of the discipline (module).

The course consists of two modules: 1. General issues of clinical pharmacology. and 2. Clinical and pharmacological approaches to the choice and use of medications in dental diseases and emergency conditions.

Mastering of discipline is carried out on laboratory lessons with the use of various forms of self-work of students, which concludes with writing of coursework aimed at use of novel achievement of clinical pharmacology in scientific and practical work of dentist.

Classroom work includes doing tests to evaluate initial level of knowledge gained at pharmacology classes. Primary attention payed to practical work using methods of active teaching: organization of discussions, solving clinical cases using analysis of risk factors of specific patients and prescribing effective and safe medications. To control knowledge gained test should be done.

Self-work is intended to further develop professional skills of students. Main type of self-work is conducting home tasks, solving situational problems, preparing scientific reports as PP presentations. At the end of the course the final test is done and the coursework “Rational pharmacotherapy of specific patient in dentistry practice” is conducted. The aim of the coursework is to gain general professional competency (GPC-6) “Being able to prescribe non-drug and drug treatment, monitor its efficacy and safety when solving professional tasks”.

To optimize learning process the TUIS system is applied. It contains short versions of lectures, methodical recommendations, description of main issues of all topics, control tests and final test, home tasks and clinical cases.

Students’ ability to use the information reference literature, resources of the global Internet network on clinical pharmacology is developed during the course of the classes.

12. Fund of estimated means for the interim assessment of students in the discipline (module).

Materials to assess the level of mastering of the educational material of the discipline «Clinical pharmacology» developed in full volume and available to students at the discipline course page on TUIS RUDN platform.

These materials (estimated means) include: list of competences with stages of their formation; description of assessment parameters and criteria of competences at different stages; description of assessment scales; sample control tasks or other materials necessary to estimate knowledge, skills and experience that characterize competence formation stages during the mastering of academic program; methodical materials that define the procedures of estimation of knowledge, skills and experience that characterize competence formation stages.

The program is developed in compliance with the requirements of the FSES HE.

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