№ ЛД-21 (ИН)

Abstract of the work program of the discipline

«Clinical pharmacology»

The main professional educational program of higher education is the specialty program in the specialty 31.05.01 General Medicine, approved on 24.05.2023.

Form of study: full-time

The period of development of OPOP IN: 6 years

Department: Pharmacology with Clinical Pharmacology

1. The purpose of the discipline: mastering the discipline of Clinical Pharmacology

2. The place of the discipline in the structure of the OOP MD: the discipline Clinical pharmacology belongs to the basic part of Block 1 of the Federal State Educational Standard in the specialty 31.05.01 Medical business

3. Requirements for the results of mastering the discipline:

The process of studying the discipline is aimed at the formation and development of competencies **PC-3 ID-2; OPK -7 ID-1.**

As a result of studying the discipline , the student must

To know:

The subject and objectives of clinical pharmacology. Sections of clinical pharmacology (clinical pharmacokinetics, pharmacodynamics, pharmacogenetics, pharmacoeconomics, pharmacoepidemiology).

The concept of pharmacotherapy. Types of pharmacotherapy (etiotropic, pathogenetic, symptomatic, preventive). The basic principles of rational pharmacotherapy (minimization, rationality, economy, controllability, individuality).

Stages of pharmacotherapy. Pharmacological and allergological anamnesis (concepts, collection rules, interpretation). Pharmacological test (concept, purpose, rules of conduct). Patient's adherence to treatment – compliance (concept, factors influencing treatment adherence, methods of increasing patient's adherence to treatment). Evaluation of the effectiveness and safety of medicines. Principles of development of programs for monitoring the effectiveness and safety of medicines. Assessment of the effect of medicines on the quality of life. Clinical pharmacokinetics. The main pharmacokinetic parameters and their clinical significance. Pharmacokinetic curve. Calculation of the loading and maintenance dose of the drug. Calculation of the dose of the drug in patients with chronic renal insufficiency. Correction of the dose of the drug in patients with impaired liver function.

Pharmacodynamics. Mechanisms of action of medicines. Antagonists, agonists, partial agonists. Target molecules of drugs (receptors, enzymes, ion channels). Types of pharmacological response: expected pharmacological response, hyperreactivity, tachyphylaxis, idiosyncrasy. The relationship between pharmacokinetics and pharmacodynamics. The concept of the therapeutic range. Therapeutic drug monitoring (indications, clinical significance, interpretation of results).

Undesirable reactions when using medications. WHO classification: reactions A, B, C, D, E. Toxic effects of drugs. Undesirable drug reactions caused by the pharmacological effects of drugs. Allergic and pseudoallergic reactions. Carcinogenicity of medicines. Drug addiction (mental and physical). Withdrawal syndrome. Risk factors for the development of undesirable drug reactions. Diagnosis, correction and prevention of undesirable drug reactions. Pharmacovigilance system. Rules for notifying drug surveillance authorities about the occurrence of undesirable drug reactions.

Interaction of medicines. Rational, irrational and dangerous combinations. Types of drug interactions. Pharmacokinetic
interaction of drugs (at the levels of absorption, distribution, metabolism, excretion). Pharmacodynamic interaction of drugs (direct and indirect). Synergism and antagonism. Interaction of medicines with food, alcohol, tobacco smoke components, herbal medicines. Risk factors of drug
interaction. Features of pharmacokinetics and pharmacodynamics of drugs in pregnant women and fetus. Categories of medicines according to the degree of risk to the fetus according to WHO: (A, B, C, D, E, X. Teratogenicity, embryotoxicity and fetotoxicity of medicines. Principles of pharmacotherapy in pregnant women. Features of pharmacokinetics and pharmacodynamics of drugs in lactating women.

Features of pharmacokinetics and pharmacodynamics of drugs in children. Calculation of the dose of the drug in children. Features of pharmacotherapy in children.

Features of pharmacokinetics and pharmacodynamics of drugs in elderly and senile patients. Calculation

of the dose of the drug in elderly and senile patients.

Clinical pharmacogenetics. Pharmacogenomics. Genetic polymorphism of the pharmacological response. Genetic factors affecting the pharmacokinetics of drugs: genetic polymorphisms of metabolic enzymes drugs (CYP2D6, CYP2C9, CYP2C19, butyrylcholinesterases, paraoxonases, N-acetyltransferases, thiopurine S-methyltransferases); genetic polymorphisms of drug transporters.Drug overdose: diagnosis, first aid, basic principles of therapy (prevention of absorption, enhanced excretion).

Clinical pharmacology of antimicrobial drugs. Antibiotics: penicillins (benzylpenicillin, oxacillin, ampicillin, amoxicillin, amoxicillin/clavulanic acid), cephalosporins (ceftriaxone, ceftazidim, cefepim), carbopenems (meropenem, doripenem), aminoglycosides (amikacin), macrolides (clarithromycin, azithromycin), lincosamides (clindamycin), tetracyclines (doxycycline), glycopeptides (vancomycin), linezolid, fluoroquinolones (ciprofloxacin, levofloxacin, moxifloxacin), cotrimaxosol, metronidazole. Antifungal: nystatin, flukanozol. Antiviral: anaferon, acyclovir, oseltamivir, interferon alpha, zidovudine, saquinavir. Arbidol. Spectrum of antimicrobial activity. Principles of choice (empirical and etiotropic), determination of the dosage regimen depending on the localization of infection and severity of the condition, kidney function. Methods for evaluating the effectiveness and safety of antimicrobial drugs. Diagnostics and prevention of NLR. A combination of antimicrobial drugs and interactions when co-administered with drugs of other groups. Clinical and pharmacological approaches, taking into account nosology, individual characteristics

Pharmacokinetics and pharmacodynamics, to the choice of antifungal and antiviral drugs.

Clinical pharmacology of psychotropic drugs. Psychostimulants (caffeine). Nootropics (piracetam). Anxiolytics and their antagonists: benzodiazepines (diazepam), flumazenil. Neuroleptics: phenothiazines (chlorpromazine), haloperidol. Antidepressants: amitriptyline, imipramine, fluoxetine. Anticonvulsant medications: carbamazepine, phenobarbital, valproic acid. Clinical and pharmacological approaches, taking into account individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for mental and neurological diseases: sleep disorders, neuroses, depression, schizophrenia, manic-depressive psychosis, epilepsy, migraine, multiple sclerosis, Parkinson's disease, transient disorders of cerebral circulation (according to ischemic or hemorrhagic types). Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with the combined administration of drugs and in combination with other drugs.

Clinical pharmacology of drugs affecting hemostasis. Antiplatelet agents: acetylsalicylic acid, clopidogrel. Direct anticoagulants: sodium heparin, low molecular weight heparin (sodium enoxaparin). Indirect anticoagulants: warfarin. Fibrinolytics: streptokinase, tissue plasminogen activator (alteplase, prourokinase). Synthetic selective inhibitor of activated factor X

(Xa) sodium fondaparinux. Drugs that increase blood clotting (vitamin K and its analogues, thrombin, hemostatic sponge, fibrinogen). Fibrinolysis inhibitors (aminocaproic acid). Preparations of iron (iron [III] hydroxide polymaltosate). Agents for stopping bleeding in patients with hemophilia (cryoprecipitate factor VIII, antihemophilic plasma, coagulation factor VII, coagulation factor IX). Etamzilate.

Principles of selection and determination of the dosage regimen depending on the state of the coagulating, anti-clotting, fibrinolytic system of the patient, data on the pharmacodynamics and pharmacokinetics of drugs and their efficacy in diseases of the liver, kidneys, gastrointestinal tract, hematopoietic organs, cardiovascular system, use in various periods of pregnancy, in lactating women and the elderly (taking into account treatment standards and the list of VED). Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups.

Clinical pharmacology of steroid anti-inflammatory drugs (salbutamol, formeterol), m-cholinoblockers (ipratropium bromide, tiotropium

bromide), xanthines (aminophyllin). Anti-inflammatory anti-asthmatic leukotriene inhibitors (zafirlukast), fenspiride. Antitussive (codeine) and expectorant (acetylcestein, dornase alpha) agents. Antihistamines (H1-histamine receptor blockers): cetirizine, loratodine. Pulmonary surfactants

(poractant alpha). Principles of drug selection, determination of routes of administration, methods of drug delivery to the respiratory tract (metered-dose inhalers, nebulizer, spacer, spinheiler, turbuhaler, dishaler) and rational dosage regimen of drugs taking into account the reversibility of airway obstruction, severity of bronchial obstruction, sputum characteristics, cardiovascular system, pharmacokinetics,

factors that change sensitivity to the drug, treatment standards and the list of VED. The concept of step-by-step therapy of bronchial asthma. Diagnosis, correction and prevention of NLR. The syndrome of decreased receptor sensitivity (tachyphylaxis, internalization and decreased regulation), causing the development of resistance to beta-stimulants, methods of its correction and prevention. Methods for evaluating effectiveness and safety. Assessment of the quality of life.

The concept of compliance (or adherence to treatment). Possible interactions with their combined administration and in combination with drugs of other groups.

Clinical pharmacology of nonsteroidal anti-inflammatory drugs. Clinical pharmacology of cytostatics and immunosuppressants. Anti-inflammatory drugs: NSAIDs (acetylsalicylic acid, ibuprofen, diclofenac, lornoxicam, rofecoxib, nimesulide), basic, slow-acting anti-inflammatory drugs (methotrexate, sulfasalazine, chloroquine, penicillamine, leflunomide). Remedies used for gout: allopurinol. Drugs that affect the structure and mineralization of bones (zoledronic acid, strontium ranelate). Painkillers (paracetamol, tramodol), opioids (morphine), ketamine, fentanyl. Clinical and pharmacological approaches, taking into account the individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for rheumatic diseases: systemic lupus erythematosus, rheumatoid arthritis, deforming osteoarthritis, osteoporosis, gout. Principles of the choice of routes of administration, dosage regimen depending on the features of the inflammatory process: localization, intensity, taking into account chronopharmacology. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups.

Clinical pharmacology of drugs affecting the organs of the digestive system. Antacids: aluminum hydroxide, aluminum phosphate, magnesium

Prokinetics: metoclopramide, domperidone. Antiemetics: ondansetron, metclopramide. Drugs for the treatment of functional disorders of the intestine (platyphylline, drotaverine). Enzyme preparations: pancreatin. Drugs used for diarrhea: loperamide.

Laxatives: bisacodyl, lactulose, hay preparations. Clinical and pharmacological approaches, taking into account individual characteristics of pharmacokinetics, pharmacodynamics,

pharmacotherapy standards in gastroenterology and the list of VED, for the selection and use of medicines for diseases of the digestive system: gastro-esophageal reflux disease, gastric ulcer and duodenal ulcer, liver cirrhosis,

chronic pancreatitis, constipation and diarrhea, irritable bowel syndrome, ulcerative colitis and Crohn's disease. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups.

Clinical pharmacology of drugs affecting vascular tone and hypolipidemic agents.. Medicinal products lowering the tone of the vessels: agonists of Central α2-adrenergic receptors and I1-imidazoline receptors (clonidine, moxonidine), α - blockers (doxazosin), ACE inhibitors (captopril, enalapril, lisinopril, fosinopril), antagonists of angiotensin receptors (losartan, valsartan, Kurdistan), direct renin inhibitor (aliskiren), β-blockers (propranolol, atenolol, metoprolol, carvedilol, bisoprolol, sotalol), slow calcium channel blockers (nifedipine, amlodipine, verepamil, diltiazem), venous dilators (nitroglycerin, isosorbide dinitrate, isosorbide mononitrate, molsidomine), pentoxifylline. Hypolipidemic drugs: statins (simvastatin, atorvastatin), fibrates (fenofibrate). Fibrinolytics (streptokinase, alteplase). Painkillers: NSAIDs, tramodol, opioids. Clinical and pharmacological approaches, taking into account individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for coronary artery disease (angina pectoris, myocardial infarction, unstable angina), hyperlipidemia and hypertension. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups.

Clinical pharmacology of drugs affecting the main functions of the myocardium and diuterica. Antiarrhythmic drugs: Class IA (quinidine, procainamide), class IB (lidocaine), Class IC (propafenone), Class II (beta blockers), Class III (amiodarone), Class VI (slow calcium channel blockers: verapamil, diltiazem), Class V (chlorine channel blockers: alinidine), Class VI (f-channel blockers: ivabradine). Inotropic drugs: cardiac glycosides (digoxin), beta-1-adrenoceptor agonists (dobutamine, dopamine, erinephrine, norepinephrine), levosimendan. Diuretics: loop diuretics (furosemide), thiazide and thiazide-like diuretics (hydrochlorothiazide, indapamide), antagonists of mineralocorticoid receptors (spironolactone, amiloride, triamterene). Clinical and pharmacological approaches, taking into account the individual characteristics of pharmacokinetics, pharmacodynamics, treatment standards and the list of VED, to the selection and use of medicines for frequent and life-threatening rhythm disorders and chronic heart failure. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups. Clinical pharmacology of drugs used in endocrinology. Antidiabetic drugs: insulins (short, medium duration, prolonged), sulfonylurea derivatives (glibenclamide, gliquidone), biguanides (metformin), alpha-glycosidase inhibitors (acarbose), thiazolidinediones (rosiglitazone), depiptidyl peptidase-4 (DPP-4) inhibitors (vildagliptin), metiglinides (repaglinide). Thyroid hormone preparations and antithyroid drugs (L- thyroxine, mercazolil, thiamazole, potassium iodide). Clinical and pharmacological approaches, taking into account the individual characteristics of pharmacokinetics, pharmacodynamics,

treatment standards and the list of VED, to the selection and use of medicines for type 1 and 2 diabetes mellitus, hypothyroidism, hyperthyroidism. Therapy of emergency conditions in endocrinology. Methods for evaluating effectiveness and safety. Diagnosis, correction and prevention of NLR. Possible interactions with their combined administration and in combination with drugs of other groups.Preclinical studies, protocol. Evidence-based medicine: principles, levels (classes) evidence. "Endpoints" of clinical trials. Meta-analysis. The importance of evidence-based medicine in clinical practice. Formulary system: principles of construction, methods of selection of medicines. The system of rational use of medicines in Russia. Federal and territorial lists of vital and essential medicines (VED). Formulary lists of hospitals. Protocols for the management of patients. Standards of diagnosis and treatment. Federal Guidelines for the Use of Medicines (formulary system). Clinical recommendations for pharmacotherapy of diseases of internal organs. The analog replacement form. Sources of clinico-pharmacological information (reference books, electronic databases, Internet resources). Clinical pharmacoepidemiology. Tasks, methods and types of pharmacoepidemiological studies. Clinical pharmacoeconomics. Criteria of pharmacoeconomical research.

Assessment of the cost of drug treatment (cost estimation). Types of pharmacoeconomical analysis.

Federal Law "On Circulation of Medicines". The role of the Ministry of Health and Social Development of the Russian Federation in the field of circulation of medicines. Organization of clinical and pharmacological service in the Russian Federation. Clinical and pharmacological service of medical institutions (principles of organization, main functions). Organization of work with medical devices and rules for their storage. Goals and objectives of the Priority National Project "Health". The principle of choosing rational pharmacotherapy in the work of doctors providing primary health care to the population. The program of additional drug provision. Fundamentals of anti-doping legislation.

Be able to:

Calculate the main pharmacokinetic parameters: volume of distribution (Vd), elimination rate constant (Kelim), half-elimination period (t1/2), clearance (Cl), bioavailability (F). Calculate the loading and maintenance doses of LV. Calculate the dose of LV in patients with CRF. To correct the dose of LV in patients with impaired liver function.

Choose effective, safe medicines in accordance with the clinical diagnosis based on pharmacotherapy standards, the list of VED, the formulary system taking into account their pharmacokinetics, pharmacodynamics, adverse drug reactions, interactions with other drugs, individual senile age), based on the results of randomized controlled pharmacoeconomical and pharmacoepidemiological studies; calculate the loading and maintenance dose of the drug; calculate the dose of drugs for patients with chronic renal failure, impaired liver function, children, the elderly and senile;

choose the dosage form of the drug, dose, route, frequency and duration of administration, determine the optimal dosage regimen for a particular patient;

develop a program for monitoring the effectiveness and safety of prescribed medicines tools by selecting the relevant complex routine (interview, examination), and a special laboratory and functional methods of research, including therapeutic drug monitoring and evaluation of indicators of quality of life, to assess the pharmacodynamic effects of drugs, their pharmacokinetic parameters; to interpret the obtained data; choose adequate methods for monitoring the effectiveness and safety of treatment and to predict the risk of NLR;to detect, classify, record drug reactions; carry out measures to increase the commitment to the patient to carry out the diagnosis and treatment of drug overdose; To justify the need to include drugs in the formulary list

Own:

The algorithm for evaluating the main parameters of pharmacokinetics of drugs by the methodology of conducting a pharmacological test. The methodology for submitting a notification of the NPR.

The algorithm for choosing the drug, dosage form and dosage regimen depending on the clinical situation

Methodology of planning and conducting CI of medicines

1. The total labor intensity of the discipline:

The total labor intensity of the discipline is 3 credits 108 hours.

2. The main issues of the discipline:

1. General issues of clinical pharmacology.
2. Clinical and pharmacological approaches to the selection and use of medicines in diseases of internal organs.
3. Evidence-based medicine.

Requirements for pharmacotherapy and drug provision according to the Priority National project "Health"

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