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Learning unit: Pharmacological propedeutics

Relevant terms

- pharmacology
  - pharmacodynamics
  - pharmacokinetics
  - molecular pharmacology
  - experimental (preclinical) pharmacology
  - clinical pharmacology
    - pharmacoepidemiology
    - pharmacoeconomics
    - pharmacogenetics/pharmacogenomics
    - pharmacovigilance
- pharmacy
- essential pharmacological terminology
  - drug
  - active substance
  - medical preparation
  - excipient/vehicle
  - drug dosage form
- names of drugs
  - chemical name of drug
  - pharmacopoeial name of drugs
  - international nonpropriatory name
  - generic name
  - brand name
- origin of drugs
  - natural

- synthetic
- semi-synthetic
- recombinant

types of therapy

- causal therapy
- symptomatic therapy
- substitution therapy

rational pharmacotherapy

- active principle vs diagnosis (efficacy)
- active principle vs patient (contraindications)
- active principle vs comedication (interactions)
- suitable posology of the drug (dose, dosing interval, time of administration)
- drug dosage form vs adherence to therapy
- pharmacotherapy costs
- primum non nocere

ATC drug classification

calculations in pharmacology

- mass concentration
- infusion rate
- therapeutic daily dose
- single therapeutic dose

Learning outcomes

Student is able to define pharmacology science and its subdisciplines and describes its clinical impact

Student knows how to use basic pharmacological terms and is oriented in the names of drugs and classification of drugs.

Student explains the basic concepts of pharmacotherapy and the rules for the rational use of drugs.

Student knows examples of substances used for individual types of pharmacotherapy

Student knows the drug databases and is able to find information on drugs from reliable on-line and printed sources.

Student knows examples of drugs of different origin.

Student is able to logically solve and practically calculate pharmacological calculations.

Study literature

Rang & Dale's Pharmacology, 9th edition, 8 chapter 1, pp. 1-4

Study materials for courses aVLFA0721p and aVLFA0721c.

Exam questions

General pharmacology: Types of pharmacotherapy, rules of rational and safe pharmacotherapy. The question of drug misuse. Pharmacology and its subbranches, origin and source of medicines, names of drugs.

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Learning unit: Drug information sources and legislation

Relevant terms

sources of information for drugs

- SÚKL - medicinal drug database
- EMA - medicinal drug database
- Pharmindex Brevíř (similar to the British National Formulary)

patient information leaflet (PIL)

summary of product characteristics (SPC / SmPC)

ATC classification

Act No. 378/2007 Coll., on Pharmaceuticals, as amended

- summary of product characteristics (SPC)
- pharmacovigilance
- adverse effect
  - serious side effect
  - unexpected side effect
- risk benefit ratio
- batch No.
- pharmacopoeia
- SÚKL
- off-label prescription

Act No. 167/1998 Coll, on addictive substances and amending certain other acts**,** as amended

- attachment 1 (§1, part a)
- attachment 5 (§1, part e)
- storage (§10)
- regulations with regard to archiving of prescription documents

Decree No. 329/2019 Coll. on prescription of medical products

- types of prescription forms

prescription form for narcotics with blue strip

common prescription form

hospital prescription form for multiple prescriptions

electronic prescription forms

rules of handling drug prescriptions

rules of of handling blue strip drug prescriptions

prescription rules

lenght of validity for drug prescription forms

RMP

IPP

Learning outcomes

The student knows basic legislation acts/decrees related to drugs.

The student can write a valid prescription form with all formal requirements.

The student is able to use on-line drug databases.

The student knows, where to find sources of drug information necessary for drug prescription.

References

Act No. 167/1998 Coll

Act No. 378/2007 Coll.

Decree No. 329/2019 Coll.

(http://www.sukl.eu/sukl/legislation-of-the-czech-republic?highlightWords=vyhl%C3%A1%C5%A1ka+54%2F2008)

Study materials for courses aVLFA0721p and aVLFA0721c.

Exam questions

General pharmacology: 4. Basic legislation related to drug use. Sources of information on drugs and medicinal products.

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Learning unit: Clinical research and trials

Impact of the learning unit:

This unit aims to introduce the necessary processes required before the drug enters clinical practice and to present the principles of clinical research within the field of new drug discovery and development. Physicians are also experts on drugs, and thus, basic information about clinical trials is considered as general pharmacological knowledge. This information may also help with the future involvement in clinical research.

Relevant terms

life cycle of a drug

clinical trial phase I

clinical trial phase II

clinical trial phase III

clinical trial phase IV

informed consent

clinical study protocol

marketing authorization of a medicinal product

patent protection

generics

biosimilars

original drugs

European Medicines Agency

State Institute for Drug Control

Good manufacturing practice (GMP)

Good clinical practice (GCP)

Declaration of Helsinky

Learning outcomes

Students are able to summarize and explain the course of testing before a new drug enters clinical practice. Student describes the life cycle of a drug.

Students are knowledgeable about the issue of clinical research, explains the aim of particular phases of clinical trials and essential ethical principles.

Students can explain, which regulation authority decides that the drug receives a marketing authorization and what kind of data the regulation authority needs for the decision.

Students are able to use the terms “original drugs”, “generics”, and “biosimilars” correctly and explains the differences in clinical research and authorizations between originals and generics.

Students can explain the meaning and principles of GMP and GCP.

Study literature

Rang & Dale's Pharmacology, 9th edition, 2020, chapter 60, pp. 750-755

Study materials for courses aVLFA0721p and aVLFA0721c.

Exam questions

General pharmacology: 3. Preclinical and clinical trials, stages.

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Learning unit: Preclinical trials

Impact of the learning unit:

This unit aims to introduce the processes of drug research and development before a new medicine enters clinical trials. Physicians are also experts on drugs, and thus, basic information about the preclinical phase of research is considered as general pharmacological knowledge. This information may also help with the future involvement in either academic or commercial preclinical research.

Relevant terms

life cycle of a drug

in silico methods in drug development

in vitro techniques of drug testing

- molecular pharmacology
- cell line (cell culture)
- isolated organ

animal model

- experimental animal, species
- principle of 3R, Project of animal experiments

toxicological testing of new drugs

- acute, subchronic, chronic toxicity
- lethal dose test
- skin toxicity
- mutagenicity, carcinogenicity
- teratogenicity

Learning outcomes

The student is able to summarize and explain the course of testing before a new drug enters clinical practice. Student describes the life cycle of a drug.

The student is knowledgeable about the issue of preclinical research, explains the aim of animal use in drug development and essential ethic principles.

Study materials

Rang & Dale's Pharmacology, 9th edition, 2020, chapter 60, pp. 750-755

Study materials for courses aVLFA0721p and aVLFA0721c.

Exam questions

General pharmacology: 3. Preclinical and clinical trials, stages.

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Learning unit: Drug dosage forms

Relevant terms

- classification of drug dosage forms
  - shape specific/shape non-specific
  - divided/undivided
- solid drug dosage forms
  - tablets
  - capsules
  - oral powders
  - adspersion powders
  - suppositories
  - vaginal globules
  - medicinal teas
  - granulates
  - implants
- liquid drug dosage forms
  - liquids administered on the skin
  - oral liquids
  - ear drops
  - nasal drops
  - ocular drops and waters
  - injections
  - infusions
- semi-solid drug dosage forms
  - ointments
  - creams
  - gels

pastes

medicated patches

transdermal plasters

gaseous drug dosage forms

aerodispersions

inhalational preparations

controlled release (2nd generation of drug dosage forms)

susteined release

prolonged release

pulse release

targeted biodistribution (3rd generation of drug dosage forms)

Learning outcomes

Students know drug dosage forms for both mass production and individual preparation of medical products classified by the pharmacopoeia.

Students recognize the individual drug dosage forms and knows their advantages and disadvantages, and typical groups of drugs administered in these drug dosage forms.

Students can explain differences among generations of drug dosage forms and their properties.

Students can compare differences among drug dosage forms – particularly with respect to the pharmacokinetics of drugs.

Students can choose suitable drug dosage forms for different groups of patients according to knowledge on properties and differences among the individual drug dosage forms.

Study literature

L. Landa et al. Selected chapters from general pharmacology for students of general medicine and dentistry at FM MU, Chapter 3, pp. 48-77

Study materials for courses aVLFA0721p and aVLFA0721c.

Exam questions

General pharmacology: 5. Solid and gaseous pharmaceutical drug dosage forms - overview and their influence on pharmacokinetics and pharmacodynamics; 6. Semi-solid and liquid pharmaceutical drug dosage forms - overview and their influence on pharmacokinetics and pharmacodynamics.

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Learning unit: Routes of drug administration

Important terms

- local effect
- systemic effect
- invasive administration route
- non-invasive administration route
- enteral administration
  - oral
  - rectal
- parenteral administration
  - injectable
    - intravenous
    - subcutaneous
    - intramuscular
    - intraosseous
  - non-injectable
    - implants
    - inhalation
    - sublingual
    - transdermal
    - buccal
    - transnasal
- local administration
  - intravesical
  - oral
  - intra-articular
  - intra-aural

conjunctival

intrathecal

factors influencing the selection of drug route of administration

drug dosage form (pharmaceutical dosage form)

actual pathophysiological state

physical-chemical properties of a drug

benefit:risk ratio

comorbidities

comedication

innovations in drug administration routes

Learning outcomes

Student knows the differences between invasive and non-invasive routes of drug administration and is able to name their benefits and risks.

Student knows the differences between enteral and parenteral routes of drug administration, is able to name their benefits and risks and give examples of clinical situations in which they can be used.

Student is able to describe certain routes of drug administration, knows their benefits and give examples of drugs administered via these routes.

Student knows factors influencing the selection of particular routes of drug administration, and is able to justify the selection of these routes of administration for specific clinical situations.

Student is oriented in novel routes of drug administration, and novel drug dosage forms.

Study materials:

Rang & Dale's Pharmacology, 9th edition, 2019, chapter 9, pp. 124-127

L. Landa et al. Selected chapters from general pharmacology for students of general medicine and dentistry at FM MU, Chapter 3, pp. 48-77

Exam questions

General pharmacology: Routes of drug administration – overview, characteristics

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Learning unit: Principles of biological therapeutics

Relevant terms

targeted therapy

biological treatment

white blood cell growth factors
red blood cell growth factors
interferons
hormones
monoclonal antibodies against soluble proteins
monoclonal antibodies against receptors and surface antigens (CD)
fusion proteins

gene therapy
somatic cell therapy
principles of the development and production of biologicals

- recombinant proteins
- PEGylation
- production of monoclonal antibodies

nomenclature of monoclonal antibodies

pharmacokinetics of biologics, routes of administration

- target-mediated drug distribution
- saturation pharmacokinetics
- dose-dependent Cl and Vd
- specifics of dosing of biological treatment

Learning outcomes

Student characterizes targeted and biological therapy and explains general differences between conventional and biological therapy.

Student explains what is gene therapy and somatic cell therapy. Student describes advantages and disadvantages of biological therapy.

Student explains the principles of recombinant production of drugs and production of monoclonal antibodies.

Student describes the influence of PEGylation on biologic drug pharmacokinetics.

Student has general knowledge about specific groups of biologics, names some agents and their indications.

Study materials

Rang & Dale's Pharmacology, 9th edition, 2020, chapter 5 (How drug acts:Biopharmaceuticals and gene therapy)

Ho R. J. Y. and Gibaldi M.: Pharmacology, Toxicology, Therapeutic Dosage Formulations, and Clinical Response. In: Biotechnology and Biopharmaceuticals. ISBN 0-471-20690-3

Study materials for courses aVLFA0721p and aVLFA0721c.

Exam questions

General pharmacology: 30. Principles of biological therapy – classification, technology, examples of use

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Learning unit: Prescription of medical products

Impact of the learning unit:

This learning unit is focused on prescription of ready-made medical products (and marginally on prescription of individually prepared preparations) including the corresponding legislation. Understanding of the general rules of prescription writing is crucial, and prescription of ready-made preparations is essential for physicians working in clinical practice.

Relevant terms

RMP

IPP

over the counter drugs (OTC)

restricted distribution OTC drugs (reserved for sale in pharmacies)

prescription

validity of prescription

symbols on prescription form

legislation

prescription of medical products containing narcotic substances (list I) and psychotropic substances (list II)

ATC classification

prescription for repeated use

Learning outcomes

Students can prescribe RMPs.

Students recognize different prescription forms and know how to use them.

Students know of IPP and RMP prescription differences.

Study literature

Hadasova et al.: Textbook Practicals in Pharmacology

Study materials for courses aVLFA0721p and aVLFA0721c.

Exam questions

General pharmacology: 4. Basic legislation related to drug use, Sources of information on drugs and medicinal products.

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Learning unit: Drug information sources and legislation

Impact of the learning unit:

Students will gain knowledge on current drug legislation and to know the relevant sources of information which tells us about the relevant properties of drugs, and their pharmacokinetics and pharmacodynamics, which is essential for future doctors, for safe and effective pharmacotherapy. Students will be aware of drug databases and know how to search for particular drugs online.

Relevant terms

sources of information for drugs

- pharmacopoeia
- SÚKL - medicinal drug database
- AISLP - medicinal drug database
- EMA - medicinal drug database
- Pharmindex Brevíř (similar to the British National Formulary)

patient information leaflet (PIL)

summary of product characteristics (SPC / SmPC)

Decree No. 54/2008 Coll.

- Types of prescription forms
    - prescription form for narcotics with blue strip
    - common prescription form
    - hospital prescription form for multiple prescriptions
    - electronic prescription forms

rules of handling drug prescriptions

rules of handling blue strip drug prescriptions

prescription rules

length of validity for drug prescription forms

Act No. 167/1998 Coll, on addictive substances and amending certain other acts**,** as amended

- attachment 1 (§1, part a)
- attachment 5 (§1, part e)
- storage (§10)
- regulations with regard to archiving of prescription documents
-

Act No. 378/2007 Coll., on Pharmaceuticals, as amended

- summary of product characteristics (SPC)
- pharmacovigilance
- adverse effect
    - serious side effect
    - unexpected side effect
- risk benefit ratio
- batch No.
- pharmacopoeia
- SÚKL
- off-label prescription

Learning outcomes

The student knows basic legislation acts/decrees related to drugs.

The student can write a valid prescription form with all formal requirements.

The student is able to use on-line drug databases.

The student knows, where to find sources of drug information necessary for drug prescription.

References

Act No. 167/1998 Coll

Act No. 378/2007 Coll.

Decree No. 54/2008 Coll.

(http://www.sukl.eu/sukl/legislation-of-the-czech-republic?highlightWords=vyhl%C3%A1%C5%A1ka+54%2F2008)

Government regulation No. 463/2013 (updated 30/2018)

Study materials for courses aVLFA0721p and aVLFA0721c.

Exam questions

General pharmacology: 4. Basic legislation related to drug use, Sources of information on drugs and medicinal products.

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Learning unit: Basics of pharmacokinetics

Important terms

movement of drug molecules across biological membranes within the body

- diffusion through the phospho-lipid bilayer
- diffusion through membrane pores
- carrier-mediated transport
    - facilitated transport
    - active transporters

binding of drugs to plasma proteins

pharmacokinetic processes

pharmacokinetic parameters

primary parameters

secondary parameters

invasion of drug

drug absorption

- maximum concentration of drug achieved in plasma (c_{max})
- time needed to achieve maximum plasma concentration (t_{max})
- bioavailability (F)
    - absolute
    - relative
- bioequivalence
- area under the curve (AUC)
- absorption rate constant (k_a)

pre-systemic elimination

- first-pass effect
- P-glycoprotein
- cytochrome P450

distribution of drugs

- rate of distribution
- distribution equilibrium
- volume of distribution (Vd)
- redistribution

drug elimination

- clearance (Cl)
- elimination rate constant (k_e)
- elimination half-life ($T_{1/2}$)

1st order kinetics (linear kinetics)

zero order kinetics (non-linear kinetics, saturation kinetics)

drug metabolism

- phase 1 reactions
- phase 2 reactions
    - cytochrome P450
        - induction of P450
        - inhibition of P450
- genetic polymorphism of biotransformation enzymes
- biodegradation and bioactivation of drugs and prodrugs

drug excretion

- alteration of excretion
- renal excretion
    - glomerular filtration
    - tubular secretion
- tubular reabsorption
    - acidification/alkalization of urine
- liver excretion
    - enterohepatic recirculation
- minor routes of drug excretion
    - breast milk
    - hair
    - saliva

factors affecting pharmacokinetic processes

pharmacokinetic interactions

Study materials:

RITTER, James, R. J. FLOWER, Graeme HENDERSON, Yoon Kong LOKE, David J. MACEWAN a H. P. RANG. *Rang and Dale's pharmacology*. Ninth edition. Edinburgh: Elsevier, 2020. xvi, 789. ISBN 9780702074486. Chapters 9, 10, 11.

Landa L. et al. Selected chapters from general pharmacology for students of general medicine and dentistry at FM MU https://portal.med.muni.cz/article-721-selected-chapters-from-general-pharmacology-for-students-of-general-medicine-and-dentistry-at-fm-mu.html

Handouts and lecture No. 3

Exam questions

General pharmacology: 8. Drug absorption, presystemic elimination, drug bioavailability, 9. Drug distribution, volume of distribution, redistribution. General principles of drug movement through the body, 10. Drug elimination, processes of the first and zero order, drug accumulation, 11. Drug biotransformation – stages, examples, 12. Drug excretion (ways of excretion, possibilities of their influence)

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Learning unit: Basics of applied pharmacokinetics

Impact of the learning unit

To gain knowledge of principles, and differences of single, repeated and continuous drug administration and understand the relationships between the pharmacokinetic parameters related to these application approaches, which is essential for rational pharmacotherapy. The kinetic models will help you to familiarize yourself with the interpretation of pharmacokinetic parameters. The general principles and limitations of therapeutic drug monitoring will be explained. The student is able to understand the basics of population pharmacokinetics, and its importance in the modelling of drug concentrations in plasma using pharmacokinetic software (passive knowledge, understanding of the problem).

Important terms

time course of drug concentration in plasma

therapeutic range

single dose administration of drug

- lag time

intermittent (repeated) drug administration

- intravascular
- extravascular
- drug accumulation
- loading dose
- maintenance dose
- steady-state plasma concentration ($c_{ss\ plateau}$)
- dosing interval
- $c_{max\ plateau}$, $c_{min\ plateau}$

continuous drug administration

- steady-state plasma concentration (c_{ss})

compartment models

- one-compartment model
- two-compartment model

therapeutic drug monitoring (TDM)

population pharmacokinetics (description, advantages, disadvantages for clinical practice)

Learning outcomes

Students can explain pharmacokinetic principles and pharmacokinetic parameters of single dose, repeated and constant-rate drug dosing; can explain the time course of drug concentration in plasma related to these dosing regimens.

Students can explain the compartment theory in pharmacokinetics.

Students are able to define the properties of drugs, which are indicated for TDM, can explain preconditions necessary for correct performing of TDM.

Students know the benefits and limitations of TDM.

Study materials

Rang & Dale's Pharmacology, 8th edition, 2016, chapter 10, pp. 125 – 132

Study materials for courses aVLFA0721p and aVLFA0721c.

Exam questions

General pharmacology: 13. Therapeutic monitoring of drugs (TDM), 14. Pharmacokinetics of single, repeated and continual drug administration

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ning unit: Pharmacodynamics

Impact of the learning unit:

Knowledge of general pharmacological principles is essential for further study of pharmacology and individual pharmacotherapeutic groups. It makes it easier for students to understand special chapters in pharmacology, to understand and then to anticipate possible drug interactions at the level of pharmacodynamics and to estimate possible risks while co-administering drugs.

Important terms

pharmacodynamics
mechanism of action
- specific
- non-specific
- receptor
- non-receptor

receptor theory
- affinity (potency)
- intrinsic activity (efficacy)
- receptors
    - according to signal transmission
        - ligand-gated ion channels
        - G-protein coupled receptor
        - receptor kinases
        - intracellular (nuclear) receptors
    - according to synaptic localization
        - autoreceptors

- ligands
    - agonist
        - full
        - partial
        - inverse
    - antagonist
    - antagonism
        - competitive
        - non-competitive
        - reversible
        - irreversible
        - chemical
        - physiologic

- allosteric modulation
- second messengers
- translocation of receptors
    - up regulation
    - down regulation
    - internalisation of receptors

dose

- single, daily, maximum daily
- threshold, sub-threshold
- effective, toxic, lethal

dose-response curves
spare receptors
change in effect after repeated administration

- desensitisation
- tolerance
- tachyphylaxis
- rebound phenomenon

synergism

- summation, potentiation
    - one-sided, double-sided

Learning outcomes

Student knows basic types of mechanisms of drug action and explains the receptor theory of drug action.

Student knows the general principles of drug action at the level of organism, organs and molecular level.

Student will explain the practical implications of different mechanisms of drug.

Student explains the concepts of full, partial agonism and inverse agonism; competitive, non-competitive, reversible, irreversible antagonism.

Student describes the dependence of the effect of the drug on the dose size, can draw dose-response curves.

Student explains the types of doses - single, daily, maximum daily, sub-threshold, threshold, toxic, lethal dose.

Student will describe the function of autoreceptors, homoreceptors and heteroreceptors.
Student knows possible consequences of repeated drug administration - can explain the concepts of tolerance, tachyphylaxis, up regulation, down regulation, internalisation of receptors.

Study materials:

Rang & Dale's Pharmacology, 9th edition, 2020, chapters 2, 3 and 4

Study materials for courses aVLFA0721p and aVLFA0721c.

Exam questions

General pharmacology: 15. Modes of drug action, 17. Synergism and antagonism in drug effect (pharmacokinetics, pharmacodynamics), 18. Dose – response curves, types of doses, drug anamnesis, patient‘s adherence

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Learning unit: Factors influencing drug effects

Relevant terms

Rational pharmacotherapy

- pharmacotherapeutic risk
- compliance/adherence

Factors influencing drug effects:

- physical-chemical properties of the drug
    - influence of pH, pK
    - size of molecule
    - drug transport across membranes
- drug dosage form
- drug administration route
- dose
    - calculation of the drug dose according to the body weight
    - calculation of the drug dose according to the body surface area
    - calculation of the drug dose for a child
- dosing interval, dosage regimen (posology)
- single/repeated drug administration
- drug combination
- drug interactions
- drug interactions with food
- body weight of the patient
- age of patient
    - pharmacotherapy in paediatrics
        - differences in pharmacokinetics
        - differences in pharmacodynamics
        - pharmacotherapy in neonatology
        - contraindicated drugs
        - Rey's syndrome
        - paradoxical reaction
        - drug dosing in paediatrics
            - calculation with the use of interpolation
            - calculation according to the adult dose
        - drug dosage forms and dosing regimens in paediatrics
    - pharmacotherapy in the elderly
        - differences in pharmacokinetics
        - differences in pharmacodynamics
        - polypharmacy
        - drug lists
            - FORTA (Fit fOR The Aged) classification

                - STOPP/START criteria
                - Beers list
- polymorbidity
    - impact on pharmacokinetic parameters
    - impact in pharmacodynamics

- pharmacogenetics/pharmacogenomics
    - idiosyncrasy
    - gene polymorphism (genetic polymorphism)
    - common gene polymorphism
    - single nucleotide polymorphism (SNP)
    - genotyping
        - variant allele
        - wild allele
    - phenotyping
        - poor, intermediate, rapid, extensive metabolisers
    - important gene polymorphisms in clinics
        - CYP2D6, CYP2C9, CYP2C19, MTHFR, TPMT enzymes
        - MDR1, BCRP transporters
        - VKORC1
    - Clinical Pharmacogenetics Implementation Consortium (CPIC)
    - Personalized medicine (precision medicine)

- circadian rhythms
- pregnancy
    - pharmacokinetic changes
        - distribution
            - placental barrier
                - P-glycoprotein
        - elimination
    - foetal ontogenetic development/sensitivity to drugs effect
    - teratogenicity
    - embryotoxicity
    - myometrium contractility – unsuitable medication
        - drugs increasing uterine tonus
        - drugs decreasing uterine tonus
    - drugs contraindicated/recommended for pathologies related to pregnancy
        - gestational diabetes
        - hypertension
        - eclampsia
        - thromboembolism
- lactation
    - blood-breast milk barrier
    - influence of pK and pH on drug transport
    - galactokinetics/galactostatics
    - Pregnancy and Lactation Labeling Rule (PLLR)

Defined learning outcome

Students will describe features of the dose-response curve

Students will explain different types of doses – single therapeutic dose, daily dose of drug, maximum daily dose, subthreshold dose, threshold dose, above threshold dose, toxic dose, and lethal dose

Student will explain consequences of administering different drug dosage forms and how they change pharmacokinetics and pharmacodynamics (quantitative and qualitative differences)

Student will explain the terms: tolerance, tachyphylaxis, allergy, up-regulation, down-regulation, internalization of the receptors

Student will be aware of the consequences of repeated drug administration

Students are able to categorize drug dosage forms according to the drug generation and protocols given in Pharmacopoeia

Student will be able to list factors influencing drug effects associated with the organism and with the drug

Student will explain the principles of drug pharmacokinetics via zero order elimination and via first order elimination

Student will describe the primary and secondary pharmacokinetic parameters

Student will list factors influencing pharmacokinetics and will be able to describe these factors in more detail

Student will explain the compartmental theory of drug distribution

Student will explain the processes of drug absorption, distribution, biotransformation and elimination

Student will explain the importance of pharmacokinetic parameters used in clinical practice

Students know pharmacokinetic principles of continuous and repeated drug administration

Students know basic principles of drug transport into and within the organism

The student is able to describe the term pharmacogenetics, gene (genetic) polymorphism, he knows the molecular basis of these disciplines. He is able to define the diferences between pharmacogenetics and pharmacogenomics. The student is aware of the clinical impact of the presence of variant alleles on the efficiency of the encoded proteins. He knows about the existence of population differences in the occurrence of variant alleles. The student is able to explain the terms phenotyping, genotyping , slow, intermediate, rapid metabolisers, variant and wild allele. The student is able to describe the examples of gene polymorphisms influencing the pharmacokinetics and pharmacodynamics of the drug with clinical impact.

Recommended electronic study sources

Rang & Dale's Pharmacology E - Book **|** Humphrey Rang, 9th edition, 2020 – chapter 12

Individual variation, pharmacogenomics and personalised medicine, subsection Epidemiological Factors and Inter-Individual Variation of Drug Response,subsection Population pharmacokinetics

http://search.ebscohost.com/login.aspx?direct=true&db=nlebk&AN=1160493&lang=cs&site=ehost-live

Exam questions

General pharmacology: 22. Factors influencing the drug effect – examples, 23. Pharmacotherapy in the elderly, the influence of comorbidities on drug effects, polypharmacy, 24. Pharmacotherapy in paediatric population, in breastfeeding women. Drugs influencing breast feeding, 25. Pharmacotherapy in pregnancy, drug teratogenicity, 26. Pharmacogenetics, influence of genetic polymorphisms on pharmacokinetics and pharmacodynamics of drugs.

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Learning unit: Adverse effects of drugs

Relevant terms

adverse effects type

- A
  - acute toxicity
- B
  - types of allergic reactions on drugs (hypersensitivity)
  - anaphylaxis
  - idiosyncratic reaction
  - genetic polymorphism
- C
  - chronic toxicity
- D
  - teratogenicity
  - embryotoxicity
  - carcinogenicity
  - mutagenicity
- E
  - rebound effect

examples of each type of adverse effects
toxicology testing in the preclinical phase of drug development

Learning outcomes

Student can differ between side and adverse effects.

Student is able to characterize the types of adverse effects according to their mechanism of induction, give examples and their treatment or prevention.

Student explains the basis of drug allergy and idiosyncratic reaction and gives examples.

Student explains the terms teratogenicity, carcinogenicity, and mutagenicity.

Student can explain, from which stage of drug research and development this safety information comes from and how is the drug safety profile investigated.

Student explains the mechanisms behind rebound effect (rebound phenomenon), gives examples and clinical relevenace of this effect.

Information sources

Rang & Dale's Pharmacology, 9th edition, 2020, chapter 58

Study materials for courses aVLFA0721p and aVLFA0721c.

Exam questions

General pharmacology: 19. Adverse drug reactions (types, categories, examples)

MUNI
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Learning unit: Pharmacovigilance

Relevant terms

dose-effect relations

- effective and toxic dose
- lethal dose
- therapeutic range
- therapeutic index

phamacovigilance

- adverse reaction
- adverse event
- serious adverse event
- unexpected adverse event
- suspected unexpected serious adverse event
- EudraVigilance database
- reporting to the regulatory authorities

Clinical trial phase IV

Learning outcomes

Student explains the terms therapeutic index, therapeutic range, and therapeutic risk.

Student evaluates safety of an example drug using therapeutic index and therapeutic range parameters.

Student distinguishes between serious and non-serious, between expected and unexpected adverse effect of drugs.

Student is able to describe the characteristics of a phase IV clinical trial of medicinal products.

Student describes subjects involved in the system of collecting and evaluating information about the adverse effects of drugs and can describe the role of the physician and his responsibilities in this system.

Study literature

Rang & Dale's Pharmacology, 9th edition, 2020 – chapter 58

Study materials for courses aVLFA0721p and aVLFA0721c.

Exam questions

General pharmacology: 20. Pharmacovigilance, drug safety