ODESSA NATIONAL MEDICAL UNIVERSITY
DEPARTMENT OF DRUGS TECHNOLOGY

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«27» august 2021 y.

METHODICAL DEVELOPMENT OF INDEPENDENT WORK OF STUDENTS (IWS)

Course 5 Faculty of Pharmaceutical

Course Biopharmacy

Topic №7 «**Procedure for preclinical study of drugs, requirements for the conditions of preclinical studies.»**

Methodical recommendations on IWS developed by:
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Methodical recommendations of IWS were discussed at the methodical meeting of the department
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Protocol № 1

Odessa - 2021

Topic: "The procedure for preclinical studies of drugs, requirements for the conditions of preclinical studies." - 4 years

Objective: To deepen knowledge in considering the procedure for conducting preclinical studies of drugs, the requirements for the conditions of preclinical studies.

Basic concepts: Preclinical studies.

Plan

I. Theoretical questions for the lesson:

ORDER

conducting preclinical studies of drugs, requirements for the conditions of individual studies

The procedure for conducting preclinical studies of medicinal products, requirements for the conditions of certain studies have been developed in accordance with Article 6 of the Law of Ukraine "On Medicinal Products".

1. TERMS

1. Preclinical study of drugs involves chemical, physical, biological, microbiological, pharmacological, toxicological and other scientific studies to study their specific activity and safety.

2. Preclinical study of drugs involves the implementation of chemical, physical, biological, microbiological, pharmacological, toxicological and other scientific studies to establish specific and general pharmacological activity, as well as harmlessness to the body of active substances and finished drugs.

3. Preclinical study is an integral part of the drug development process. The characteristics of specific pharmacological activity and safety during use and in relation to its possible long-term consequences established by the results of preclinical study are fundamental factors that determine the possibility of transferring the drug to commercial release and the feasibility of its medical use.

Regulating and control functions on the organization and conduct and to identify the necessary volumes preclinical studied - tion medicines performs Pharmacological Committee of Ministry of Health of Ukraine.

Clinical trial conducted special purpose - vanymy research databases (institutions, organizations and businesses - we are), the list of which is determined based on certification of the norms applied in international practice.

Certification of databases of preclinical study of drugs and control over their activities in order to facilitate compliance with the requirements for planning and conducting research, the order of registration of results obtained by the Pharmacological Committee of the Ministry of Health of Ukraine through the Center for Preclinical Study of Medicines and relevant expert groups.

Control of materials (report) of preclinical study of a medicinal product on observance of methodical requirements, necessary volumes and reliability is carried out by specialized expert commissions of the Pharmacological Committee of the Ministry of Health of Ukraine. In the case of pre-clinical study of drugs for non-certified research databases or subject to preclinical studies specialized agencies -

we have other countries that are not certified by the standards of OR obtained D - from entrepreneurs to be controlled by the Center preclinical study drugs Pharmacological Committee of the Ministry of Health of Ukraine on their compliance with the requirements .

Preclinical studies of drugs can be performed on a contractual basis. Copyright, property and non-property rights related to the pre-clinical study of medicines are regulated by law.

2. PROCEDURE FOR PRECLINICAL STUDIES OF MEDICINES

1. The order of preclinical studies is determined according to the rubrication of drugs in the following groups:

I. Medicines from new pharmacological substances.

II. Known drugs with a new route of administration.

III. Known drugs with fundamentally new approaches to dosing.

IV. Drugs with altered technology for obtaining known pharmacological substances without changing the type and composition of the dosage form.

V. Medicines based on resynthesized pharmacological substances (by known technology).

VI. Combined drugs that contain two or more known pharmacological substances.

VII. Drugs are combined, which, along with the known ones, contain new pharmacological substances.

VIII. Drugs with a change in the composition of subsidiary Pharmaceuti - these substances on the basis of known pharmacological substances in a certain dosage form.

IX. Medicines recommended for new indications without changing the type, composition of the dosage form and mode of administration.

X. Medicines registered in the former USSR before 01.12.91, NTD for which are developed in Ukraine.

XI. Drugs produced by domestic technology with Viko - ristaniya imported pharmaceutical substances and (or) import headlights - matsevtychnyh substances suitable dosage forms which are registered in Ukraine if the former Soviet Union.

XII. Drugs manufactured by the licensed technology using pharmacological and pharmaceutical substances, the doctor - schimi shape for registration in Ukraine or of the former - it is the Soviet Union.

XIII. Homeopathic medicines.

XIV. Drugs manufactured by the new technology of Use - Tanna import tabletmasy, granules, appropriate dosage forms which are registered in Ukraine if the former Soviet Union.

XV. Medicinal products manufactured using a new technology using imported pharmacological substances and (or) imported pharmaceutical substances, the relevant dosage forms of which are registered in Ukraine or in the former USSR.

XVI. Medicines made from "in bulk" (packaging of the finished dosage form), registered in the form "in bulk".

2. The volume of preclinical studies that must be conducted to submit materials to the Pharmacological Committee of the Ministry of Health of Ukraine for further examination is determined according to these I-XVI groups of drugs and is the same for domestic and foreign drugs (studies are conducted as needed).

1. Medicines from new pharmacological substances: *Harmlessness*

1. Acute toxicity to three species of animals;
2. Subacute toxicity;
3. Chronic toxicity;
4. Local irritant and (or) ulcerogenic action;
5. Possible cumulative effect;
6. Possible allergenic properties;
7. Toxic effect on the immune system;
8. Teratogenicity; embryolethality; fetotoxicity; gonadotoxicity;
9. Possible mutagenic properties;
10. Possible carcinogenic effect;
11. Drug dependence: if necessary; necessarily - for fundamentally new drugs;
12. Treatment of poisoning in case of overdose in the experiment.

Pharmacological activity

1. Specific activity according to several criteria;
2. General pharmacology.

Pharmacokinetics

2.2.2. Known drugs with a new route of administration: *Harmless*

1. Acute toxicity in one species of animal;
2. Subacute toxicity;
3. Local irritant and (or) ulcerogenic action.

Pharmacological activity

1. Specific activity according to several criteria. *Pharmacokinetics*

3. Known drugs with fundamentally new approaches to dosing: *Harmlessness*

1. Acute toxicity to three species of animals;
2. Subacute toxicity;
3. Chronic toxicity;
4. Local irritant and (or) ulcerogenic action;
5. Possible cumulative effect;
6. Possible allergenic properties;
7. Toxic effect on the immune system;
8. Teratogenicity; embryolethality; fetotoxicity; gonadotoxicity;
9. Possible mutagenic properties;
10. Drug dependence.

Pharmacological activity

1. Specific activity according to several criteria;
2. General pharmacology.

Pharmacokinetics

1. Dynamics of suction and excretion;
2. Bioavailability.

4. Drugs with modified technology for obtaining known pharmacological substances without changing the type and compositionof the dosage form:

Harmlessness

1. Acute toxicity on one species of animals when the drug is administered in dosage form;
2. Subacute toxicity;
3. Local irritant and (or) ulcerogenic action;
4. Possible allergenic properties.

Pharmacological activity

1. Specific activity.

Pharmacokinetics

Medicines based on resynthesized pharmacological substances (by known technology):

Harmlessness

1. Acute toxicity on one type of animals when administered drug in dosage form compared to the dosage form based on origami - tional substance;
2. Subacute toxicity;
3. Local irritant and (or) ulcerogenic action;
4. Possible allergenic properties.

Pharmacological activity

1. Specific activity.

Pharmacokinetics

Combined drugs that contain two or more known pharmacological substances:

Harmlessness

1. Acute toxicity to three species of animals;
2. Subacute toxicity;
3. Chronic toxicity;
4. Local irritant and (or) ulcerogenic action;
5. Possible cumulative effect;
6. Possible allergenic properties;
7. Toxic effect on the immune system;
8. Teratogenicity; embryolethality; fetotoxicity; gonadotoxicity;
9. Possible mutagenic properties;
10. Drug dependence: if necessary.

Pharmacological activity

1. Specific activity according to several criteria;
2. General pharmacology.

Pharmacokinetics

1. Dynamics of suction and excretion;

2. Bioavailability.

7. Drugs are combined, which, along with the known ones, contain new pharmacological substances:

Harmlessness

1. Acute toxicity to three species of animals;
2. Subacute toxicity;
3. Chronic toxicity;
4. Local irritant and (or) ulcerogenic action;
5. Possible cumulative effect;
6. Possible allergenic properties;
7. Toxic effect on the immune system;
8. Teratogenicity; embryolethality; fetotoxicity; gonadotoxicity;
9. Possible mutagenic properties;
10. Possible carcinogenic effect;
11. Drug dependence: if necessary; required - for prin - Tipova new drugs;
12. Treatment of poisoning in case of overdose in the experiment.

Pharmacological activity

1. Specific activity according to several criteria;
2. General pharmacology.

8. Drugs with a change in the composition of subsidiary Pharmaceuti - these substances on the basis of known pharmacological substances in a certain dosage forms:

Harmlessness

1. Acute toxicity to three species of animals;
2. Subacute toxicity;
3. Local irritant and (or) ulcerogenic action;
4. Possible allergenic properties.

Pharmacological activity

1. Specific activity by one criterion.

Pharmacokinetics

1. Dynamics of suction and excretion;
2. Bioavailability.

9. Medicines recommended for new indications without changing the type, composition of the dosage form and mode of administration.

Harmless Studies are not performed.

Pharmacological activity

1. Specific activity by one criterion;

2. Specific activity according to several criteria. *Pharmacokinetics*

10. Medicines registered in the former USSR before 01.12.91, NTD (regulatory and technical documentation) for which developed in Ukraine;

- to the Pharmacological Committee of Ministry of Health Ukraine provided mat - ly that were considered in the Pharmacological Committee of the USSR. Additional clinical trials are not performed.

Drugs produced by domestic technology, using imported pharmaceutical substances and (or) import of pharmaceutical substances suitable dosage forms which zareyest - Rowan in Ukraine if the former Soviet Union:

Harmlessness

1. Acute toxicity in one species.

Pharmacological activity

1. Specific activity by one criterion.

Pharmacokinetics

Drugs manufactured by the licensed technology using pharmacological and pharmaceutical substances, dosage forms which correspond registered in Ukraine or in co - ex USSR:

Harmlessness

1. Acute toxicity in one species.

Pharmacological activity

1. Specific activity by one criterion.

Pharmacokinetics

Homeopathic medicines:

Harmlessness

1. Chronic toxicity;
2. Possible allergenic properties.

Pharmacological activity

Pharmacokinetics

Drugs manufactured by new technology inc - a handling import tabletmasy, granules, appropriate dosage forms which are registered in Ukraine if the former Soviet Union:

Harmlessness

1. Acute toxicity in one species.

Pharmacological activity

1. Specific activity by one criterion.

Drugs manufactured by new technology inc - a handling imported pharmaceutical substances and (or) import pharma - tsevtychnyh substances suitable dosage forms which are registered in Ukraine if the former Soviet Union:

Harmlessness

1. Acute toxicity in one species.

Pharmacological activity

1. Specific activity by one criterion.

Medicines made from “in bulk” (packaging of the finished dosage form), registered in the form “in bulk”:

Preclinical studies are not performed.

Questions for self-control

1. The concept of simple chemical modification of drugs and its impact on the bioavailability and stability of drugs.

2. Classification of excipients and their role in the preparation of dosage forms. The influence of the nature of excipients on the rate of absorption of drugs and their therapeutic efficacy.
3. The influence of the dosage form on the rate of absorption of the drug, its concentration in biological fluids and the stability of drugs.
4. Ways of introduction of drugs into an organism and their influence on therapeutic activity.
5. Influence of technological factor on pharmacotherapy.
6. The concept of drug stability. The role of stabilizers in drug technology.
7. nfluence of drug storage conditions on their stability.
8. The concept of pharmacodynamics and pharmacokinetics of drugs.
9. The main biological factors influencing the absorption of drugs.
10. The influence of the physiological state of the patient on the pharmacodynamics and pharmacokinetics of drugs.
11. Variable biochemical factors. Metabolism and elimination of drugs.

Approximate tasks for the study of theoretical material

1. Make a dictionary of basic concepts on the topic

2. Fill in the orientation card for self-preparation of the student using the literature on the topic :

№ z.p.	**The main tasks**	**Instructions**	**Answers**
1.	The procedure for clinical study of drugs.	Define the term	Біофармація : підруч. для студентів закл. вищ. освіти / О. І. Тихонов [та ін.] ; за ред. О. І. Тихонова. – 2-ге вид., перероб. і допов. – Харків : НФаУ: Золоті сторінки, 2019. – 224 с
2.	Where certification of preclinical study of drugs and control over their activities is carried out.	Give an explanation	Certification of databases of preclinical study of drugs and control over their activities in order to facilitate compliance with the requirements for planning and conducting research, the order of registration of results obtained by the Pharmacological Committee of the Ministry of Health of Ukraine through the Center for Preclinical Study of Medicines and relevant expert groups.

II. Practical work (tasks) that will be performed in class:

III. Test tasks for self-control

http://info.odmu.edu.ua/chair/drugs technology / Tests Step-2 on the following topics:

-Industrial production of pharmaceutical solutions of syrups, extraction preparations. Quality assessment

-Industrial production of biogenic stimulants. Aerosols. Quality assessment

IV. Individual tasks for students on the topic of the lesson

Prepare a presentation (abstract): The main directions of improvement of drugs and development of biopharmaceutical research.

List of recommended reading

Main:

. 1. Біофармація : підруч. для студентів закл. вищ. освіти / О. І. Тихонов [та ін.] ; за ред. О. І. Тихонова. – 2-ге вид., перероб. і допов. – Харків : НФаУ: Золоті сторінки, 2019. – 224 с

2. Настанова СТ-Н МОЗУ 4242-7.1:2005 «Лікарські засоби. Настанова з клінічних досліджень. Дослідження біодоступності та біоеквівалентності» - Київ,

2018.

3. Настанова СТ-Н МОЗУ 4242-7.1:2005 «Лікарські засоби. Настанова з клінічних досліджень. Дослідження біодоступності та біоеквівалентності» - Київ, 2018.

4. Настанова СТ-Н МОЗУ 42-7.2:2018 Лікарські засоби дослідження біоеквівалентності. – Київ, 2018. – 77 с.