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Original article

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**(not exceeding 13 words, reflecting the goal, including min. 1–2 key words over the first 65 characters, study type at the end divided with a colon, e.g. “Randomised Control Trial”, “Analysis of Russian Pharmacovigilance Database” etc.)**

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**ABSTRACT** *The abstract should include as much of manuscript data as possible (150-300 words)*

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**Funding.** *For example:*

1. This study was conducted by the Scientific Centre for Expert Evaluation of Medicinal Products as part of the applied research funded under State Assignment No. \_\_\_ (R&D Registry No. \_\_\_).

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**Disclosure.** *For example:*

1. The authors have no conflict of interest.

2. Elena V. Ivanova has been a member of the Editorial Board of *Safety and Risk of Pharmacotherapy* since 2021. The other authors declare no conflict of interest.

3. The authors work for Bacteriophage JSC. However, when writing this paper, the authors were guided by considerations of the scientific value of the material obtained; the authors declare their impartiality in its assessment.

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Make sure you choose specific terminology (in BrE). Transliterarion from Russian into English is allowed only for proper names, devices and other objects that cannot be translated. Make sure you use the same terms all over the text. Active Voice is preferred over Passive Voice, i.e. “The study tested”, not “It was tested in this study”.

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**MATERIALS AND METHODS**

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*Example 1:*

Urinalysis was performed on Day 45 and 90. In order to collect urine, the rats were placed in metabolic cages (Tecniplast, Italy) for 16–24 h, with a free access to drinking water. Urine output was evaluated, as well as glucose, protein, bilirubin, urobilinogen, ketones, рН, density, white blood cells, red blood cells, and mucus. Clinical urinalysis was performed with Aution Eleven 4020 analyser (Arkray, Japan) using dipsticks. Urine protein and creatinine was found with URIСКАН-BK biochemical analyser (Ailiton, Russia). The urine was microscopically analysed using supravital staining, counting cell elements on a cell counting plate magnified 100× and 400× on DM1000 light optical microscope (Leica, Germany).

Clinical studies should be approved by ethical committees (a numbered and dated document with the name of the committee). Human studies should comply with 2013 Declaration of Helsinki. Describe what kind of informed consent was obtained (e.g. for a study participation or publishing anonymised data). If applicable, add the number of dropouts.

*Example 2:*

1. 47 subjects were included in the study. The study was approved by an independent local ethical committee of [*name of the body*] (protocol statement No. \_, ethical committee of [*institution*] as of [*date*]). Each patient signed an informed voluntary consent for the examination and treatment results to be included in the study, performed in compliance with the protocol, ethical principles of World Medical Association’s Declaration of Helsinki, a trilateral GCP agreement (ICH GCP) and current Russian legislation [*document name*].

2. Inclusion criteria were: confirmed diagnosis with specific symptoms, patients older than 18 years, and a signed informed consent.

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- describe key results, regardless of whether they support or disprove your hypothesis, confirm or contradict other researches;

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Make sure to assess initial data and results, adding absolute values (e.g. increase/ decrease or absolute difference between the groups), as well as effect size and the corresponding measures of uncertainty, e.g. confidence interval (CI). Make sure to give mean values and standard deviations for normally distributed data, as well as medians and ranges (or interquartile range, IQR) for non-Gaussian distribution. Avoid using only auxiliary values for statistical hypotheses, e.g. *p*, bearing no significant quantitative information. For most of the studies, add *p* after comparing absolute values or measures of uncertainty (e.g. 0.8%, 95% CI from –0.2% to 1.8%; *p*=0.03).

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This section may be formatted as a numbered list of conclusions (3–5 bullet points). In this case, its title should be changed to CONCLUSIONS.

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**Additional information.** The authors may provide a link to supplementary materials to the paper (figures, tables, and other files), including those placed in a repository (with their digital object identifiers (DOIs)).

**Authors’ contributions.** All the authors confirm that they meet the ICMJE criteria for authorship. The most significant contributions were as follows. *E.V. Ivanova* conceptualised the study, drafted the manuscript, formulated the conclusions, etc. *M.A. Petrova* worked with literature sources, etc. *M.N. Smirnova* carried out experiments, etc. *V.G. Sidorov* participated in formulating the conclusions and approved the final version of the manuscript for publication.

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The protocol of this observational clinical study was approved by the local ethics committee of the City Clinical Hospital No. X, Moscow Department of Healthcare (meeting minutes No. 29 of 21 October 2024).

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