COMPARATIVE ANALYSIS OF THE BRITISH AND UKRAINIAN FORMS OF MEDICINAL PRODUCTS AND THE NATIONAL LIST OF MEDICINAL PRODUCTS FOR THE PROVISION OF RATIONAL PHARMACOTHERAPY OF OSTEOARTROSIS

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Introduction. In recent years, there has been a tendency o increase in the number of patients diagnosed with osteoarthritis (OA), as well as the unceasing rejuvenation of this contingent. In different countries, the incidence varies, but the older the population of the country, the higher the prevalence of morbidity. It is considered that in the elderly it reaches 80-90%. First of all the urgency of this problem is due to the presence of pain in patients with OA and to the violation of functional joint mobility, which cause a sharp decrease in motion activity, social maladaptation, loss of working capacity, which leads to a significant socio-economic burden both for the individual patient and the state in general.

Aim. Comparative analysis of the drugs lists for the OA treatment in the formulary of Ukraine and the United Kingdom in terms of their conclusiveness.

Materials and methods. Objects of study were the National British formularies, "Manual on the algorithm of knee osteoarthrosis in Europe and in the world: report of the special committee of the European Society for the Study of the Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis - ESCEO), the State Medicines List, the National List of Medicinal Products, the protocol for the provision of medical care to patients with osteoarthrosis (Order of the Ministry of Health of Ukraine dated October 12, 2006, No. 676), the clinical instruction «Osteoarthrosis».

Results and discussion. During the study of sources, many pharmacological groups have been identified for the rational therapy of OA. It was found that at the OA pharmacotherapy the main pharmacological group for the relief of pain is the NSAIDS from the group M01A. Foreign sources suggest starting pain arresting with paracetamol 3 g / day, which has a marked analgesic effect and does not affect the metabolism of articular cartilage and symptomatic slow acting drugs for osteoarthritis – SYSADOA. According to the analysis of evidence-based medicine, it has been found that enzyme therapy is used only in Ukraine for treating OA, while foreign sources do not have this notice.

Conclusions. Comparative analysis of foreign sources of evidence-based medicine and domestic documents on the treatment of OA revealed some differences in pharmacotherapy of OA, the absence of a number of drugs in domestic documents, in particular symptomatic drugs of delayed action - glucosamine sulfate with proven efficacy.

ANALYSIS OF APPROACHES TO PREVENTIVE AND CORRECTIVE ACTION PLAN DESIGN IN CLINICAL TRIALS OF DRUGS QUALITY MANAGEMENT

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Introduction. The development of methods and approaches to quality management in the pharmaceutical field was gradually taking place with the accumulation of sufficient experience and data. The modern approach to the process of quality management of clinical trials (CT) is based on prevention of possible non-conformances during organizing and holding CT of new drugs. One of the most effective tools in this area is the corrective action and preventive action plan.

Aim. To analyze approaches to the of preventive and corrective actions plan design in the clinical trials of drugs quality management.

Materials and methods. To achieve this goal, we analyzed organizational structure and approaches to the design of 8 corrective and preventive action plans (CAPA-plans). During the analysis methods of generalization, abstraction, and system analysis were used.

Results and discussion. Out of the 8 analyzed CAPA-plans, 62.5% were foreign, 25% were designed on the basis of international audits in Ukraine and 12.5%, as a result of the audit of the CT sponsor. Among the analyzed plans, two organizational structures were used: in the form of a table (62.5%) and in the form of a description of certain non-conformances (37.5 %). Both organizational structures have the following common information: non-conformances, corrective or prevention action, and effective date. In addition to these items, the plans organized in the form of tables divide identified non-conformances to critical, major and minor; contain recommendations for the elimination of the revealed non-conformances, the identity of the person responsible for the effective and timely corrective or preventive action, and the place for the comments. As the advantages of this structure convenience of use, structuring, indicating the items of regulatory requirements, which regulates the process, etc. can be considered. Regarding the organizational form of CAPA-plans in the form of describing individual non-conformances, in addition to common points, as in the form of tables, the reason of occurrence of the identified non-conformance, the description of staff training, the effectiveness of the implementation of corrective or preventive action are additionally indicated. Significant disadvantages of this type of CAPA-plans organizational structure are the lack of indication of the severity of the identified non-conformance, as well as the inconvenience of their use.

Conclusions. The approaches to the design of CAPA-plans in CT of new drugs quality management were analyzed, which showed the advantage of such plans organizational structure in the form of tables. It is advisable to further analyze the methodological approaches to CAPA-plans design and development of standard operating procedures for organizing work on this process.

OFF-LABEL USE OF DRUGS IN TREATMENT OF ENDOMETRIOSIS

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Introduction. Expanding of indications to the use of already registered medicines allows manufacturers to save money and time as these drugs have already been tested for toxicity and safety and have no risk of recall at the initial stage of the test. FDA definition of off-label use of drugs is the use of a drug in accordance with indications, administration regimens, in dosages, in the contingent of patients or in other parameters that did not mentioned in the approved instruction. According to the statistics, about 91% of gynecologists use drugs off-label: the incidence of such appointments in pregnant women is 54%. At the same time, only 34% of specialists believe that this kind of treatment can be associated with significant risks. Among gynecological diseases, endometriosis is the presence of an outside tissue that is similar to the endometrium and causes a chronic inflammatory reaction - ranks the third place in the incidence rate. The disease occurs most often in women of reproductive and working age (frequency of occurrence and prevalence is 5-10%), accompanied by pain and occasionally leading to infertility. Drug treatment represents by different groups of drugs, none of which provides for the elimination of symptoms, persistent therapeutic effect and reliable prevention of relapse, which is associated with a fragmentary understanding of the pathogenesis of endometriosis.

Aim. The purpose of our work is to expand the indications for the use of combined oral contraceptives (COCs) for endometriosis due to off-label drugs. In Ukraine, patients remain unprotected if doctors prescribe drugs outside the approved indications of use indicated in the instructions. According to the order of the Ministry of Healthcare of Ukraine No. 1422 from 2017, the Ukrainian doctor has the opportunity to work according to international guidelines for treatment and diagnosis.

Materials and methods. Analysis of the normative basis for the use of off-label COCs in women suffering from endometriosis in Ukraine and in the world.