Revista de Enfermagem
do Centro-Oeste Mineiro
2018; 8
DOI: 10.19175/recom.v8i0.3227
www.ufsj.edu.br/recom

NURSING PERSPECTIVES IN THE DEVELOPMENT OF CLINICAL RESEARCH IN ONCOLOGY

Giovana Paula Rezende Simino - Nurse. PhD in Medicines and Pharmaceutical Assistance. Master of Science. Specialist in Oncology. Currently Adjunct Professor at the Federal University of Minas Gerais - Nursing School.

Malignant neoplastic diseases are a public health problem due to the high incidence, prevalence, and individual and social impacts caused. From this perspective, many drugs, devices, and techniques are researched continuously to improve the quality of life, survival, cure, and treatment of people affected by these diseases.

Nurses coordinate and conduct clinical studies based on the management of signs and symptoms presented as a result of the treatments and devices used, and from the malignant neoplasia itself. It is worth mentioning that 60% of patients currently diagnosed with malignant neoplastic diseases present advanced stages of the diseases, stages III and IV. Furthermore, there are existing socioeconomic characteristics that require nurse contributions to develop new accessible technologies with possible incorporation into the Unified Healthcare System (SUS).

Clinical researches are instrumental in evaluating the efficacy and safety of drugs for humans. Conducting these studies requires the knowledge of nurses regarding the ethical procedures of good clinical practice (GCP) and the method of randomized clinical trials. The GCPs must follow an ethical and scientific quality standard in force in the national and international context for designing, conducting, recording, and reporting clinical studies.

Therefore, it is necessary to know the phases of a clinical study. Clinical researches can be subdivided into four phases. Phase I, in which the clinical research is aimed at the small group of generally healthy volunteers to evaluate the preliminary safety of an intervention; and Phase II, which consists of a preliminary study conducted with approximately 100 to 200 patients to evaluate the efficacy, safety, and bioavailability of the drugs. Phase III, comprises researches with patients in greater quantity (300 to 3000 participants), allowing the knowledge of the types and profiles of adverse reactions. In Phase IV, the research is directed to the post-marketing surveillance of the product to establish its beneficial value and discover new adverse events for the patient profile to which the drug, device or other new technology is being applied.

The research requires knowledge of the ethical legislation in force in our country, emphasizing that, for all clinical phases of the research, the interventions must be evaluated and approved by a Research Ethics Committee (REC) and, in the case of multicenter studies, also by the National Commission for Research Ethics (NCRE), which complies with Resolution 466/2012 of the National Health Council. These

organs have professionals from different formations as collegiate members (health and social sciences professionals, representatives of the judiciary, representatives of healthcare users) to assess and issue opinions. It is worth mentioning that all members are volunteers and premised on the private judgment of research projects. The clinical research nurse ensures the participants of the study a consented and volunteer participation, as well as their integrity in the face of adverse events, which should be notified to the REC.

The registration of all clinical trials must be done in the database of the Brazilian Registry of Clinical Trials (BRCT), according to the ANVISA Resolution - RDC 36, of June 27th, 2012 (clinical studies phases I, II, III, and IV).

Even though it is still in the consolidation process, nursing researchers have contributed to the coordination of technological innovation outside the scope of industries (the most significant labor market for nurses in clinical research), in public research centers, and universities. These researches have great potential for managing of signs and symptoms in oncology, as well as for training nurses to conduct clinical trials as researchers.

REFERENCES

1. Aguiar, DF; Camacho, KG. O cotidiano do enfermeiro em pesquisa clínica: um relato de experiência. Rev. Esc. enferm. USP, São Paulo , v. 44, n. 2, p. 526-530, June 2010 . Disponível em: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0080-62342010000200040&lng=en&nrm=iso>. access on 28 Oct. 2018. http://dx.doi.org/10.1590/S0080-62342010000200040

2. Ferreira, EB ; Ciol, M ; Vasques, CI ; Bontempo, PSM ; Pires, NN ; Silva, LFOE. ; Avelino, SR ; Santos, MA; Reis, PED. Gel of chamomile vs. urea cream to prevent acute radiation dermatitis in patients with head and neck cancer: a randomized controlled trial. Journal of Advanced Nursing (Print), p. n/a-n/a, 2016.

3. Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. RESOLUÇÃO RDC Nº 36, DE 27 DE JUNHO DE 2012.

4. Brasil. Instituto Nacional de Câncer José Alencar Gomes da Silva. Coordenação de Prevenção e Vigilância. Estimativa 2018: incidência de câncer no Brasil / Instituto Nacional de Câncer José Alencar Gomes da Silva. Coordenação de Prevenção e Vigilância. – Rio de Janeiro: INCA, 2017.

Como citar este artigo:
Sirmino GPR. Perspectivas da Enfermagem no Desenvolvimento de Pesquisas Clínicas em Oncologia. Revista de Enfermagem do Centro Oeste Mineiro. 2018;8:eEditorial. [Access _____]; Available in: _____.DOI: http://dx.doi.org/10.19175/recom.v8i0.3227