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The Role of Study Nurses in Clinical Trials of IBD Drugs

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Abstract

Objective: To explore the establishment and roles of study nurses in IBD drug clinical trials. **Methods**: The management experience of this department's study nurses in IBD drug clinical trials was retrospectively analyzed. **Results**: The study nurses played very important roles at all links during the preliminary preparation of IBD drug clinical trials, the whole-process management after project initiation, and the later work of project conclusion. **Conclusions**: As direct participants in drug clinical trials, study nurses play a very important role in ensuring standardization of the trial process, safeguarding patient's rights and safety, and assisting investigators in carrying out study works smoothly.

Keywords

Drug Clinical Trial, Study Nurse, Inflammatory Bowel Disease, IBD Specialist Nurse

1. Introduction

Inflammatory bowel disease (IBD), including ulcerative colitis and Crohn's disease, is a group of chronic non-specific inflammatory diseases of the intestines with unknown etiology. In the past 10 years, the number of IBD patients has increased significantly. It is estimated that the number of IBD patients will reach 1.5 million in China by 2025 [1]. IBD patients need long-term medication to maintain remission of this incurable disease. The treatment methods fall into 2 categories: The first is conventional medication, including aminosalicylic acid, thiopurines, hormones, methotrexate, etc. The second is biological agents, including infliximab, vedolizumab, etc. [2] [3] [4].

With the development of immunology and in-depth research on the pathogenesis of IBD, new drug R&D has been successively initiated. Some drugs have

entered into global multi-center phase II and III clinical trials. These drugs may gradually compensate for the inadequacy of currently marketed drugs to provide IBD patients with more treatment options [5]. With national policy support for new drug development in recent years, the number of clinical trials conducted in China has grown rapidly, including new drug for the treatment of IBD. Drug clinical trials have become an important part of the work contents of clinicians and study nurses in hospitals. Large institutions are staffed with full-time study nurses to assist in the management of drug clinical trials. Internationally, the role of study nurses has been discussed to a certain extent. It is generally believed that the role of nursing care at each stage of clinical trials is very broad. As shown by the survey results of study nurse work contents conducted by an international organization "Association of Clinical Research Professionals" (ACRP) in 2005, study nurses' work involved 128 tasks under 11 categories. The scope of study nurses' responsibility involved all aspects of clinical trials except for diagnosis and treatment of the subjects [6]. However, the specific details varied from countries where the study nurses were located and departments of the hospitals. The Department of Gastroenterology in our hospital was granted national drug clinical trial base by the Ministry of Health in 2012. In the past 5 years, it has undertaken nearly 30 global multi-center phase II and III clinical trials of IBD drugs. Our department assigned full-time a study nurses to participate in the whole-process management of drug clinical trials, and gradually established and improved related management systems and work responsibilities. This article shared our experience through reviewing the clinical practice of study nurses in clinical trials of IBD related drugs in our department in recent years.

2. Assisted the Sponsor in Completing Preliminary Preparatory Works for Project Initiation at the Site

1) Assisted the sponsor in study site questionnaire survey before project establishment, assisted in collecting personal data of principal investigator, sub-investigators and study nurses, as well as qualification certificates of relevant department and equipment in the hospital, and the range of normal values, etc.

2) Assisted in formulating project contracts, providing materials, and rationally applying for materials, because various projects may require common instruments, it was necessary to avoid provision of duplicate instruments by different project teams in order to reduce resource waste.

3) Assisted project team in submitting ethical materials according to hospital requirements, and in completing preliminary review of project contracts, as well as the review and stamping process in relevant hospital departments.

4) Prepared and participated in project kick-off meeting. Arranged and coordinated the meeting time and place, and notified relevant personnel of the department to attend the meeting. Once the project contract was signed, the materials were in place, and the kick-off meeting was held, patient screening process could be initiated.

3. Carried out Whole-Process Management after Project Initiation

3.1. Study Nurses Followed up with IBD Clinic of the Department

Assisted investigators in preliminary patient screening at outpatient clinic, verified the inclusion and exclusion criteria, and assisted investigators in conducting informed consent with patients who have initially met the inclusion and exclusion criteria.

"Informed consent" was a process to explain clinical trial details using daily language instead of medical terminology, including study background, mechanisms of drug action, previous safety and efficacy data, common adverse reactions, study visit schedule, confidentiality of personal data, withdrawal from the trial at any stage without being discriminated by doctors, expected patient benefits, potential risks, etc.

Study nurses needed to be familiar with the trial protocol, mechanism of drug action, study background, benefits, and risks. Like investigators, study nurses needed to master the mechanism of drug action, study background, subject's benefits, and risks. Understanding mechanism of action and study background of the new drug could help investigators better answer patient's questions and do a better job during the informed consent process. A signed informed consent form needed to be obtained from subjects after the consent process. The patients were to decide whether to participate after fully understanding this trial through adequate communication. The subjects fully understood the trial and chose to participate on a completely voluntary basis. This not only improved subject's compliance and sense of security but also reduced potential medical disputes at later stage. Davis et al regarded study nurses as the guarantor or protective umbrella of subject's rights and interests [7]. In the case of subject's indemnity claims related to serious adverse events, study nurses assisted subjects and the sponsor in active communication to protect subject's rights and interests.

3.2. Whole-Process Management of Subjects

After the subjects have been randomized into the groups, the visit time, blood sampling and medication during the visit were arranged. In the meantime, the subjects were properly educated on taking medication according to dosage specified in the protocol during each visit. For projects involving oral administration at home, under-medication and over-medication frequently occurred, resulting in protocol violation. The infusion rate and time, and the observation time in hospital after the infusion must be ensured for intravenously administered drugs. The subjects should also be reminded of the time for next hospital visit. Some projects lasted up to 2 - 3 years. Study nurses needed to keep in touch with the subjects at any time to improve subject's compliance. This helped the subjects actively cooperate with the investigators to complete relevant examinations and follow-ups according to the protocol. At ending of the induction period of an IBD project, the randomized drug delivery system determined wheth-

er there was a response to treatment based on scoring of the symptom diary card filled out by the subjects every day. When repeated randomization and administration were involved, the study nurses must reconfirm subject's understanding of filling out the diary card and its importance at each visit.

3.3. Whole-Process Management of Project Materials

3.3.1. Management of Study Drugs

It was necessary to understand drug storage conditions, distribution or dispensing standards, permissible concomitant treatment and prohibited drug combination, and termination criteria. In terms of validity period of the study drug, because the study drugs used in foreign company sponsored projects were generally shipped from abroad, inspection and quarantine at the Chinese customs may take some time. Therefore, in order to ensure adequacy of drug quantity and sufficiency of the validity period, the study site needed to apply for study drugs from the sponsor in advance based on its own speed of patient enrollment.

3.3.2. Management of Project Equipment and Instrument

IBD drug clinical trials usually require the use of physical testing instruments such as thermometer, sphygmomanometer, and electrocardiograph. Special equipment included low-temperature refrigerator for storing subject's blood samples, centrifuges for centrifuging subject's blood samples, and incubator for preserving special specimens. The relevant equipment and instruments were cleaned and disinfected daily. Regular application for instrument and equipment calibration was filed to ensure the quality of sample determination.

4. Project Conclusion

After project completion, the data were sorted and archived according to the documentation required to be stored by clinical trial institution. Study nurses assisted the investigators in completing study summary report and submitting ethical conclusion report. Study nurses also needed to count the project materials for recovery, and verify study costs together with the sponsor.

5. Summary

In European and American countries, study nurse posts must be created in clinical trials. Study nurses indispensably occupy a central and coordinating position, while nursing care has become a profession in clinical research [8]. IBD is a chronic and recurring disease without cure at the present time. The disease accompanies patients for a life time and requires long-term medication. If some patients benefit, they may continue to participate in clinical trials of other IBD drugs. Therefore, ensuring subject's good participating experience in clinical trials will increase their willingness to be involved in new drug projects again to a certain extent. The study nurses of this department are also IBD specialist nurses responsible for the follow-ups of IBD patients, that is, continued nursing care outside the hospital; at usual time, they keep very close contact with the IBD pa-

tients. During clinical trials, the study nurses are the subject's contact persons at any time, the communication hub between subjects and investigators, and the defender of subject's rights and interests. In fact, this department has properly integrated study nurses and IBD specialist nurses into one so that the study nurses can have drug clinical trial knowledge and professional expertise for the treatment and nursing care of IBD at the same time; in practice, they play an indispensable role in IBD drug clinical trials.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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