Clinical Research Support Center

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General Summary

Clinical Research Support Center was founded in April 2014 to promote the proper conduct of clinical research. The center has the following functions: protocol planning, statistical analysis, data management, monitoring, support for clinical research conduct, and education. We started consulting for clinical research in September 2014 and had 39 protocols of consultation from April 2017 through March 2018. Consultations were as follows: 21 protocols for protocol planning and statistics (objective of the research, study design, control arm, study participants and their recruitment method, randomization, primary endpoint and its rationale, procedure to avoid/reduce bias, data collection, stopping criteria, statistical analysis, analysis sets, and sample size calculations),1protocol for randomization/allocation/concealment of emergency key, 18 protocols for the statistical analyses,10 protocols for the preparation of article, 4 protocols for response to reviewers after the submission of articles (including additional analyses), 5 protocols for application of AMED or Ministry of Education, Culture, Sports, Science and Technology, and 13 protocols for conducting statistical analysis. Consultations were requested by Endoscopy, Psychiatry, Surgery, Cardiovascular Surgery, Division of Nephrology and Hypertension, Anesthesiology, Cardiology, Diabetes, Metabolism and Endocrinology, Pediatrics, Breast and Endocrinology Surgery, Urology, Neurosurgery, Clinical Oncology/Hematology, Radiology, Gene therapy, Centre for International Affairs, Orthopaedic Surgery, Innovation for Medical Information Technology, Regeneative Medicine.

In cooperation with the Division of Clinical Pharmacology and Therapeutics we held "Clinical Trial Seminar" 3 times to improve literacy about clinical trials among researchers. The themes were "Ethical guidelines for medical and health research involving human subjects." (April 2017), "Basic knowledge on randomized controlled trials." (May 2017), "Roles of prostaglandin D/J in the vascular systems.", "From vascular endothelial research to investigator-initiated registration trials — role of clinical pharmacology — ." (November 2017). We also held a "Biostatistics Seminar for Tomorrow" consisting of 2 basic courses and 2 advanced courses to promote appropriate trial designs and the application of biostatistical methods.

Ethical guidelines for medical and health research involving human subjects have been implemented since April 2015. In these guidelines the principal investigator is obliged to perform monitoring if interventional studies are invasive. To meet this demand, we prepared standard operating procedures for monitoring. The monitoring is performed by clinical research coordinators themselves or by supported investigators.

We introduced a clinical research liaison system to facilitate clinical research. We requested departments conducting many clinical trials to assign liaison physicians. Liaison physicians are invited to participate with priority in the "Biostatistics Seminar for Tomorrow" and are expected to act as liaisons between the department to which they

belong and the Clinical Research Support Center.

Research Activities

Statistical methods of analyzing competing risks data

In the analysis of survival data, an individual is subjected to an event due to only 1 of several distinct types of causes, and the occurrence of 1 type omits other types of causes, such as death due to stroke and death due to myocardial infarction. These event types are given the statistical term "competing risks."

Considering discharge in hospitalized patients, reason of discharge is not always improved condition of patients. Some patients are discharged from hospital due to worsening condition, and others are due to death. The reasons of discharge are competing risks. In hospital management research, reasons of discharge are hardly taken into account to evaluate the duration of hospital stay of hospitalized patients. We consider it important to show an appropriate analysis in such a case. We examined the applicability of nursing care needs indexes (NCNI) as a criterion for judging discharge recommendation date. Using available sample data to evaluate duration of hospital stay, we explored the association of NCNI and the time to cause-specific discharge by a statistical program developed in 2016 for competing risks analysis. The data included left truncated data, which are usually not observed in clinical trial but frequently observed in clinical research. We explored a statistical method to treat left truncated data in the analysis of competing risks and modified the statistical program to evaluate duration of hospital stay in the sample data appropriately.

Publications

Abe T, Morita K, Shinohara G, Hashimoto K, Nishikawa M. Synergistic effects of remote perconditioning with terminal blood cardioplegia in an in vivo piglet model. *Eur J Cardiothorac Surg.* 2017; **52:** 479–84.