Clinical Research Support Center

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General Summary

The 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. In April 2019, the directorship changed from Prof. Kageyama to Prof. Shikishima. We started consulting for clinical research in September 2014 and had 81 protocols of consultation, including 40 new protocols, from April 2019 through March 2020. The number of protocols the center newly consulted on was as follows: research planning, 23; protocol planning and statistics, 19; protocol for randomization/allocation/concealment of emergency key, 4; consultation of statistical analyses, 20; conducting statistical analysis, 1; preparation of articles, 1; application for competitive research fund, 10; and specified clinical research, 5. The number of protocols the center continuously consulted on was as follows: protocol planning and statistics, 2; protocol for randomization/allocation/concealment of emergency key, 1; consultation of statistical analyses, 7; conducting statistical analysis, 7; preparation of articles, 7; application for competitive research fund, 2; and specified clinical research, 2. As a result, 4 articles were published and 2 studies were approved for competitive research funding.

In cooperation with the Division of Clinical Pharmacology and Therapeutics we held a "Clinical Trial Seminar" to improve literacy about clinical trials among researchers. Since April 2019, the "Clinical Trial Seminar" was held by our center. The themes were "Basic knowledge on clinical study" (December 2019) and "Approval review and consultation regarding pharmaceuticals in the Pharmaceuticals and Medical Devices Agency" (January 2020). We stopped holding a "Biostatistics Seminar for Tomorrow," consisting of 2 basic courses and 1 advanced course, which had been held since 2015 to promote appropriate trial designs and the application of biostatistical methods. Starting this, we have instead held "Methodology for Clinical Trial" as a course for graduate students which is open to all staff members of The Jikei University School of Medicine.

Ethical guidelines for medical and health research involving human subjects have been implemented since April 2015. In addition, the Clinical Trials Act has been enforced since April 2018, and a certified review board was established at The Jikei University in November 2018. To meet these requirements, we prepared common forms of protocol, an informed consent form, a standard operating procedure for monitoring, and other documents. This year, we upgraded the ethics application system to address the requirements of the Clinical Trials Act. In addition, clinical research coordinators appointed by the director of The Jikei University Hospital monitored the specified clinical trials ongoing in our hospital to check whether researchers conduct them properly.

As a measure against disasters, a clinical data extraction system from electronic health

records was introduced in the 4 affiliated hospitals of The Jikei University by using the Standardized Structured Medical-record Information eXchange. We have started to establish a disease registry based on this system in cooperation with medical departments.

Research Activities

Owing to the nature of our center, we collaborate with researchers to conduct various types of clinical studies. In cooperation with the Division of Diabetes, Metabolism and Endocrinology, Department of Internal Medicine, we showed that the monthly achievement rates of hemoglobin A1c, blood pressure, and level of low-density lipoprotein (LDL) cholesterol and of all 3 variables have certain circannual rhythms in type 2 diabetes mellitus of 4,678 patients nationwide. As part of the Japan Diabetes Clinical Data Management Study Group, we used those patient records whose hemoglobin A1c, blood pressure, and LDL cholesterol were measured 12 or more times during a 24-month period from January 2013 through December 2014. We explored related factors to lowering achievement rates in summer and winter separately. Insulin use and sulfonylurea use were independently associated with the decreased achievement rates of all 3 variables in both summer and winter.

In cooperation with the Division of Nephrology and Hypertension, Department of Internal Medicine, we analyzed retrospective cohort of 1,065 Japanese patients with IgA nephropathy diagnosed between 2002 and 2004. This study was funded by the Agency for Medical Research and Development (AMED). We showed that the matched patients who underwent tonsillectomy within 1 year of the initial diagnosis of IgA nephropathy had a lower risk of renal events than those who did not undergo the procedure, and that tonsillectomy may improve renal survival rates in patients with IgA nephropathy independent of conventional therapy using renin-angiotensin system inhibitors and corticosteroids.

In cooperation with the Departments of Endoscopy, we made a study protocol of randomized controlled trial to examine the accuracy of diagnostic support system using artificial intelligence for colonoscopy. Under the support of the AMED, we started the study with the approval of the certified review board and finished the planed enrollment. We undertook to develop the analysis program.

Publications

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