

Research Center for Medical Sciences

Division of Clinical Pharmacology and Therapeutics

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General Summary

The Division of Clinical Pharmacology and Therapeutics was established in July 1995. The aim of the division is to investigate drug treatment, mainly in the area of internal medicine, whereas other departments of clinical pharmacology in Japan focus on registration trials, particularly phase I trials. Because a clinical laboratory where we had performed many human pharmacological studies became unavailable in 2003, we shifted our research from human studies to multicenter clinical trials and pharmacoepidemiological studies.

Research Activities

So far, we have performed a large-scale pharmacoepidemiological study on the safety of statins. It took quite a long time to complete it, therefore, we organized a research group comprising academic and industrial organizations (Japanese Society for Pharmacoepidemiology, Japanese Society of Clinical Pharmacology and Therapeutics, Japan Association for Medical Informatics, Japan Society of Clinical Trials and Research, Federation of Pharmaceutical Manufacturer's Associations of Japan, Pharmaceutical Research and Manufacturers of America, and European Federation of Pharmaceutical Industries and Associations Japan) to make postmarketing studies more efficient by utilizing the Standardized Structured Medical-record Information eXchange (SS-MIX). The SS-MIX system was started in 2006 as a project supported by the Ministry of Health, Labour and Welfare for promoting the exchange of standardized medical information. The SS-MIX system will increase the efficiency of pharmacoepidemiological studies by identifying "new users" who started the drug after some period of nonuse. The "new user" design is often essential for unbiased results. In the 3 Jikei University Hospitals (Katsushika Medical Center, Daisan Hospital, and Kashiwa Hospital) where electronic medical record systems have already been installed, we are going to collect prescription and medical test data. Prescription and medical test data as of January 2016 have been incorporated into SS-MIX, we made diabetes registry. We are planning to broaden disease registries to various diseases.

To raise the literacy of clinical trials among researchers we held "Clinical Trial Seminar" 3 times this year. The themes were as follows: "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).

An administrative office for registration trials was established in the hospital in February 1999, and the system for registration trials in the hospital has been reformed to meet the demands of the new good clinical practice guidelines. Ten clinical research coordinators (CRCs) now facilitate clinical trials of which 2 CRCs have been involved in monitoring as well. The CRCs have started to help with both registration trials and investigator-initiated trials. The CRCs have been introduced into all registration trials since 2004; the quality and speed of these trials were much improved.

Investigator-initiated registration trials which was managed by other medical institutions have been conducted so far. In 2017 an investigator-initiated registration trial which was designed & planned by an investigator of the Jikei University has been conducted. In this trial management of the trial was outsourced to contract research organization (CRO).