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

Statins (3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors) have been widely used to treat hyperlipidemia. They have adverse effects on muscle, the liver, kidneys, and other organs. To investigate the incidence of these adverse effects and antihyperlipidemic effects, we performed a pilot study in 3 major hospitals, including our hospital, according to a case-cohort study design in which detailed data were collected in all cases and in a subcohort representing 5% of the whole sample. A full-scale study has been performed with a large sample size of 20,000 patients.

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 (GCP) guidelines. Seven clinical research coordinators (CRCs) — 6 nurses and 1 pharmacist — now facilitate clinical trials. The CRCs have started to help with both registration trials and investigator-initiated trials. CRCs have been introduced into all registration trials since 2004; the quality and speed of these trials were much improved.

The Ministry of Health, Labour and Welfare started a New 5 Yearly Clinical Trial Action Plan to help registration trials to cope with trials done abroad. This action plan selects 10 core hospitals and 30 major clinical trial institutions. The Jikei University Hospital applied to be a major clinical trial institution and was accepted. According to this plan, we reinforced CRCs and introduced a data manager to improve the clinical trial system. We also introduced an information technology system to processing registration trial management.

Publications

Kitazawa S (Teikyo-Heisei Univ), Tsutani K[1] ([1]Tokyo Univ), Orii T (Kanto Medl Cent NTT EC), Masada M (Fukui Univ), Kageyama S, Ebihara T (RAD-AR Council), Yamamura S (Josai Int Univ), Goto N (Meijo Univ), Santa T[1], Hashiguchi M (Keio Univ). A survey of the position of pharmacoepidemiology in pharmacy education in Japan (in Japanese). *Yakuzaiekigaku* 2009; **14:**

13–20.

Reviews and Books

Kageyama S. Interpretation of clinical trials on antihypertensive drugs—endpoints and composite endpoints in PROBE design (in Japanese). *Medical Practice* 2009; **26:** 981–4.