

## Division of Clinical Pharmacology and Therapeutics

---

Shigeru Kageyama, *Professor and Director*

### 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 design in which detailed data were collected from all cases and in a subcohort representing 5% of all subjects. A full-scale study has been performed with a large sample size of 7,000 patients from 68 institutions.

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. 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 was named a major clinical trial institution. 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. However, because of budgetary problems, this program was ended in our hospital 1 year earlier than scheduled.

### Publications

**Saito I<sup>1</sup>, Suzuki H<sup>2</sup>, Kageyama S, Saruta T<sup>1</sup>** (*<sup>1</sup>Keio Univ, <sup>2</sup>Saitama Med Sch*). Effect of anti-hypertensive treatment on cardiovascular events in

elderly hypertensive patients: Japan's benidipine research on anti-hypertensive effects in the elderly (J-BRAVE). *Clin Exp Hypertens* 2011; **33**: 133-

40.

### Reviews and Books

**Kageyama S.** Hypertension in relatively young adults and women with low risks or without organ damages (in Japanese). *Medicina* 2010; **47**: 1144-7.

**Kageyama S.** Glycaemic control in diabetes complicated with dyslipidaemia and hypertension (in Japanese). *Nihon Iji Shinpo* 2010; **4500**: 50-3.

**Kageyama S.** Treatment of diabetes in patients complicated with dyslipidaemia and hypertension (in Japanese). *Mebio* 2010; **27(10)**: 78-85.

**Kageyama S.** Thiazolidinedione derivatives (in Japanese). In: Kageyama S, Kubota K, editors. *Yakuzaiekigaku no kiso to jissen*. Osaka: Iyaku Janarusha; 2010. p. 61-9.

**Kageyama S.** Registration trial (in Japanese). In: Kageyama S, Kubota K, editors. *Yakuzaiekigaku no kiso to jissen*. Osaka: Iyaku Janarusha; 2010. p. 259-64.