

Department of Pharmacovigilance

1. Staffs and Students (April, 2010)

Professor	Masayoshi Harigai	
Associate Professor	Ryuji Koike,	Toshihiro Nanki
Assistant Professor	Michi Tanaka,	Kaori Watanabe
Graduate Student	Ryoko Sakai,	Hayato Yamazaki
Research Nurse	Shoko Kawase	
Secretary	Tomoko Takahashi	

2. Purpose of Education

Department of Pharmacovigilance has established since 2005 and dedicated to pharmacovigilance activity in the field of rheumatology. Main objective of Department of Pharmacovigilance in the graduate course is to provide students opportunity to study basics of pharmacoepidemiology including clinical statistics and to implement epidemiological studies in pharmacovigilance using some databases which have been maintained by this department.

3. Research Subjects

1. Registry of Japanese rheumatoid arthritis patients on biologics for long-term safety (REAL study)
2. Safety of biologics in clinical use in Japanese patients with rheumatoid arthritis in long-term (SECURE study)
3. Pulmonary infections in patients receiving immunosuppressive treatment for rheumatic diseases (PREVENT)
4. Retrospective study of pulmonary complications in patients with rheumatic diseases
5. Identification of susceptibility genes associated with anti-neutrophil cytoplasm antibody-associated vasculitis in Japanese
6. Effectiveness and safety in clinical practice of abatacept in Japanese patients with rheumatoid arthritis
7. A prospective cohort study of early arthritis in clinical practice evaluating development of rheumatoid arthritis (PRECEDE)
8. International symposium for safety of biologics in patients with rheumatoid arthritis
9. Biologics-free Remission after Stopping Adalimumab in Japanese Patients with Rheumatoid Arthritis study (BRIGHT study)

4. Clinical Service

All Members of Department of Pharmacovigilance are rheumatologists and engaged in clinical services in the field of rheumatology as specialists.

5. Publications

Original Article

1. Katsumata Y, Harigai M, Kawaguchi Y, Fukasawa C, Soejima M, Kanno T, Nishimura K, Yamada T, Yamanaka H, Hara M. Diagnostic reliability of magnetic resonance imaging for central nervous system syndromes in systemic lupus erythematosus: a prospective cohort study. *BMC Musculoskelet Disord.* 11:13, 2010.
2. Yamazaki H, Nanki T, Miyasaka N, Harigai, M. Methotrexate and trimethoprim-sulfamethoxazole use for PCP prophylaxis. *J Rheumatol.* (in press)
3. Sakai R, Komano Y, Tanaka M, Nanki T, Koike R, Nakajima A, Atsumi T, Yasuda S, Tanaka Y, Saito K, Tohma S, Fujii T, Ihata A, Tamura N, Kawakami A, Sugihara T, Ito S, Miyasaka N, Harigai M, for the REAL Study Group. The REAL database reveals no significant risk for serious infection during treatment with methotrexate over 8 mg/week in patients with rheumatoid arthritis. *Mod Rheumatol.* (in press)
4. Koike R, Tanaka M, Komano Y, Sakai F, Sugiyama H, Nanki T, Ide H, Jodo S, Katayama K, Matsushima H, Miwa Y, Morita K, Nakashima H, Nakamura H, Natsumeda M, Sato Y, Semba S, Tateishi M, Miyasaka N, Harigai M. Tacrolimus-induced pulmonary injury in rheumatoid arthritis patients. *Pulm Pharmacol Ther.* (in press)
5. Kaneko K, Nanki T, Hosoya T, Mizoguchi F, Miyasaka N. Etanercept-induced necrotizing crescentic glomerulonephritis in two patients with rheumatoid arthritis. *Mod Rheumatol.* 20: 632-636, 2010.
6. Watanabe K, Penfold MET, Matsuda A, Ohyanagi N, Kaneko K, Miyabe Y, Matsumoto K, Schall TJ, Miyasaka N, Nanki T. Pathogenic role of CXCR7 in rheumatoid arthritis. *Arthritis Rheum.* 62: 3211-3220, 2010.
7. Sato A, Watanabe K, Kaneko K, Murakami Y, Ishido M, Miyasaka N, Nanki T. The effect of synthetic retinoid,

Am80, on T helper cell development and antibody production in murine collagen-induced arthritis. *Mod Rheumatol.* 20: 244-251, 2010.