

THISIS TITLE THE PROSPECTIVE STUDY OF ADVERSE DRUG REACTION OF  
ANTI-TUBERCULOSIS DRUGS IN THAI PATIENTS

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#### ABSTRACT

In this study, adverse drug reactions of antituberculosis drugs were monitored in Thai patients suffering from pulmonary tuberculosis. The methods of monitoring included intensive hospital monitoring in the Anti-tuberculosis Association of Thailand Hospital under the Royal Patronage of H.M. the King, Bangkok, Thailand and spontaneous report system operated by National Adverse Drug Reaction Monitoring Center (NADRM) of the Thai FDA. During the period between January 1 -December 31, 1988, there were 15,844 patients attending out - patient clinic of The Anti-tuberculosis Association of Thailand Hospital. Only 304 patients were considered to be eligible for this study. Adverse reactions occurred in 12.5% of the study population. Dermatological manifestations including skin rash, urticaria, pruritus, and Steven Johnson Syndrome were the most common reactions found. Most of reactions were considered to be mild in severity (83%). One patient died due to severe allergic reaction induced by a combination therapy of isoniazid and rifampicin. Age and sex did not seem to have any significant effect on development of adverse drug reaction (ADR). Analysis of spontaneous report collected by the Thai Food and Drug Administration (FDA) indicated that 11% of total adverse drug reaction reports received were due to antituberculosis drugs. More

types of adverse effects were reported than those found in intensive hospital monitoring study. Out of 216 cases reported, 4 patients died of Steven Johnson Syndrome with severe complication due to a combination of isoniazid and thiacetazone. Unexpected adverse effects of antituberculosis drugs were not identified in this study and being expected based on their pharmacological properties and there are no evidences to suggest that Thai patients respond differently to antituberculosis drugs from Western patients.