

Comparative studies of quality and bioavailability of methotrexate in Thai patients with rheumatoid arthritis.

Manorot M, Rojanasathien N, Louthrenoo W, Tonsuwannont W, Teekachunhatean S.

Department of Pharmacology, Faculty of Medicine, Chiang Mai University, Thailand.

The bioavailability of the two generic methotrexate oral preparations (Emtrexate, Pharmachemie Company, Holland and Methotrexate Remedica, Remedica, Cyprus as the test preparations), were compared to the innovator (Methotrexate Lederle, Lederle, U.S.A. as the reference) in 10 patients with rheumatoid arthritis. A single 7.5 mg oral dose of each preparation was given to the subjects in a randomized, double-blind, three-period crossover design with a 1 week washout period. Serum methotrexate concentrations were determined by using Fluorescence Polarization Immunoassay (Abbott TDx). No significant differences in pharmacokinetic parameters (AUC, C_{max}, and T_{max}) were observed between the test and reference preparations. The mean and 90 per cent CI of the ratio Emtrexate/Methotrexate Lederle and Methotrexate Remedica/Methotrexate Lederle of the C_{max}, AUC₀₋₈, and AUC_{0-alpha} were 0.93 (0.87-1.00), 0.9 (0.82-0.98), 0.88 (0.79-0.99) and 0.97 (0.93-1.02), 0.95 (0.90-0.99), 0.94 (0.86-1.02), respectively. These values were well within the acceptable bioequivalence range of 0.8-1.25. The mean and 90 per cent CI of T_{max} difference between Emtrexate-Methotrexate Lederle and Methotrexate Remedica-Methotrexate Lederle also overlapped the stipulated bioequivalence range of the T_{max} differences of +/- 0.25 hour. Thus, Emtrexate and Methotrexate Remedica were considered bioequivalent to the reference Methotrexate Lederle regarding the rate of absorption and the extent of absorption.

Publication Types:

- Clinical Trial
- Randomized Controlled Trial

PMID: 9916387 [PubMed - indexed for MEDLINE]

J Med Assoc Thai. 1998 Dec;81(12):978-85.



本文献由“学霸图书馆-文献云下载”收集自网络，仅供学习交流使用。

学霸图书馆（www.xuebalib.com）是一个“整合众多图书馆数据库资源，提供一站式文献检索和下载服务”的24小时在线不限IP图书馆。

图书馆致力于便利、促进学习与科研，提供最强文献下载服务。

图书馆导航：

[图书馆首页](#) [文献云下载](#) [图书馆入口](#) [外文数据库大全](#) [疑难文献辅助工具](#)