

 中文标题 检索 跨刊检索

基于人体群体药代动力学的中药上市后用法用量再评价

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作者中文名	作者英文名	单位中文名	单位英文名	E-Mail
姜俊杰	JIANG Junjie	中国中医科学院 中医临床基础医学研究所,北京 100700	Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences, Beijing 100700, China	
谢雁鸣	XIE Yanming	中国中医科学院 中医临床基础医学研究所,北京 100700	Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences, Beijing 100700, China	zhinanb2010@yahoo.com.cn

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中文摘要:现代中成药的用法用量是经过严格的I、II、III期临床试验确定的,上市后亦缺少关于用法用量再评价的深入研究。因此,临床应用中成药时,其用法用量基本固定,并没有依据个体情况调整给药剂量,这种用药方法不符合个体化治疗的理念。人体群体药代动力学可为临床个体化用药提供支持,从而实现中药上市后用法用量再评价。该文简要介绍中药上市后用法用量再评价的现状、意义,以及人体群体药代动力学在中药上市后用法用量再评价中的应用。

中文关键词:人体群体药代动力学 中药上市后评价 用法用量

Post-marketing re-evaluation about usage and dosage of Chinese medicine based on human population pharmacokinetics

Abstract:The usage and dosage of Chinese patent medicine are determined by rigorous evaluation which include four clinical trial stages: I, II, III. But the usage and dosage of Chinese patent medicine are lacked re-evaluation after marketing. And this lead to unchanging or fixed of the usage and dosage of Chinese patent medicine instead of different quantity based on different situations in individual patients. The situation of Chinese patent medicine used in clinical application is far away from the idea of the "Treatment based on syndrome differentiation" in traditional Chinese medicine and personalized therapy. Human population pharmacokinetics provides data support to the personalized therapy in clinical application, and achieved the postmarketing reevaluating of the usage and dosage of Chinese patent medicine. This paper briefly introduced the present situation, significance and the application of human population pharmacokinetics about re-evaluation of the usage and dosage of Chinese patent medicine after marketing.

keywords:human population pharmacokinetics reassessment of Chinese medicine in the post-marketed usage and dosage

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