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0期临床试验与中药注射剂上市后临床安全性再评价

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中文摘要:中药注射剂不良反应时有发生,临床安全性问题亟待解决,需要进行上市后临床安全性再评价,过敏反应是不良反应评价的主要内容之一。对含有毒药材的中成药、有安全问题的中药注射剂需要开展0期临床试验,0期临床试验使用"微剂量"研究周期内收集必要的药物安全性及药代动力学试验数据,微剂量可以反映中药注射剂的致敏情况。0期临床试验为上市后中药注射剂的安全性再评价提供了新的方法,是否进行0期临床试验,应依据品种是否有安全性问题而定,中药注射剂初始剂量以及样本含量的确定是研究设计的关键问题。

中文关键词:0期临床试验 微剂量 中药注射剂 上市后临床安全性再评价

Phase 0 clinical trials and post-marketed re-evaluation of clinical safety in injection of traditional Chinese medicine

Abstract: Adverse drug reaction induced by injection of traditional Chinese medicine(TCM) often occurs. Post-marketed re-evaluation of clinical safety in injection of TCM is indispensable,in order to solve the clinical safety problems. It is necessary to conduct Phase 0 clinical trials for containing toxic medicine and injection of TCM. Phase 0 clinical trials,involving very limited human exposure,and using microdose of drugs,are intended to collect the necessary safety and pharmacokinetic data in limited period. Microdose reflects allergies of injection of TCM. Phase 0 clinical trials provide a new method for post-marketed re-evaluation of safety in injection of TCM. Its use depends on whether there is a safety problem for injection of TCM,and the determination of initial dose and sample size are key questions in study design.

keywords: phase 0 clinical trials microdose injection of traditional Chinese medicine post-marketed re-evaluation of clinical safety

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