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皮试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:中药注射剂引起的不良反应以过敏反应最为常见,以速发型变态反应最为严重,需要进行上市后安全性再评价。皮试以筛查I型变态反应为主,不仅能够早期发现中药注射剂在人群中的致敏情况,而且是了解过敏发生机制的途径之一,对于中药注射剂的安全使用具有重要的意义。皮试主要适用于常发生I型变态反应的中药注射剂,研究人群选择健康志愿者和药品说明书中所规定的适应症患者,皮试方法可采用皮内注射法与点刺法。皮试液浓度的不同可能会影响皮试阳性率,中药注射剂皮试液配制主要参考青霉素皮试液制备方法,可设置不同剂量的中药注射剂皮试液、葡萄糖注射液或生理盐水、盐酸组胺进行对照。根据I型变态反应发生的特点,皮试观测时应密切关注30 min内的情况,观测指标应围绕中药注射剂上市后临床安全性再评价进行设计。

中文关键词:皮试 中药注射剂 上市后临床安全性再评价

Skin test: guide of post-marketed re-evaluation of clinical safety in traditional Chinese medicine injection

Abstract:Anaphylaxis is the most common adverse reaction caused by traditional Chinese medicine(TCM) injection,the most serious of which is type I,so post-marketed safety re-evaluation is necessary. Skin test can be used to screen type I allergy reaction,which is of great significance for TCM injection safe use. Skin test is not only able to find the population sensitization situation of TCM injection,but also is a way of understanding the mechanism of allergy reaction. TCM injection varieties that often occur type I anaphylaxis are applicable to skin test,and study population include healthy volunteers and patients whose disease is listed in the drug specification,intracutaneous test and prick test are the alternative method. The concentration of skin-test solution may influence the positive rate of skin test, penicillin skin-test solution preparation method can be used as the reference in TCM injection. Different doses of TCM injection skin-test solution,glucose injection and normal saline,histamine hydrochloride are comprised in comparison. Given the characteristics of type I allergy reaction,we should be pay close attention to skin test reaction in half an hour,and observation index need be designed based on post-marketed re-evaluation of clinical safety.

keywords:skin test traditional Chinese medicine injection post-marketed re-evaluation of clinical safety

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