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苦碟子注射液治疗缺血性中风急性期上市后再评价

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中文摘要:目的:评价苦碟子注射液对缺血性中风急性期患者影响的有效性和安全性。方法:采用实用性随机对照试验,通过中央随机系统,将700例缺血性中风患者随机分为试验组346例、对照组354例。试验组给予苦碟子注射液的基础上加用西医药学基础治疗和中医康复技术,对照组给予西医药学基础治疗加用现代康复技术,疗程为10~21 d。在第7、14、21天3个时间点上观察患者的神经功能缺损(NIHSS评分)和肢体运动功能(FMI评分)。同时观察2组不良事件发生率及治疗前后实验室检查指标。结果:应用广义估计方程模型,发现随着治疗时间的延长,2组NIHSS评分及FMI评分均呈改善趋势,且治疗第14天和第21天NIHSS和FMI评分试验组较对照组相比,具有显著统计学差异($P<0.05$)。试验组未发生与苦碟子注射液相关的不良事件。结论:苦碟子注射液对缺血性中风患者的神经功能缺损及肢体运动功能有一定的改善作用。苦碟子注射液在治疗缺血性中风早期康复方面是安全有效的。

中文关键词:苦碟子注射液 急性缺血性中风 上市后再评价

Post-marketing re-evaluation of Kudiezi injection study on early treatment in patients with ischemic stroke

Abstract: Objective: To study the effect and safety of Kudiezi injection on patients with acute ischemic stroke. Method: Seven hundreds patients were divided into two groups by central randomization system. The study group, 346 cases, was treated with kudiezi injection plus traditional Chinese medicine(TCM) synthesis rehabilitation project, and the control group, 354 cases, was treated with synthetic rehabilitation project. The patients were treated for 10 to 21 days. Before treatment and at the 7th, 14th and 21th day of treatment, the indexes include NIHSS used for evaluating the neurological deficit degree and the motor function score (Fugl-Meyer) for evaluating motor function were observed. The safety index is defined by adverse observation event and laboratory test. The incidence of adverse events and laboratory tests results were observed before and after treatment at the same time. Result: Application of generalized estimating equation model, we found that as the treatment time, NIHSS score and FMI score of the two groups showed a trend of improvement. And at the 14th days and 21th days of treatment, compared to the control group the treatment group showed significant statistical difference on the impact of NIHSS and FMI ($P<0.05$). No serious adverse events were observed. Conclusion: Kudiezi injection plus TCM rehabilitation program of ischemic stroke showed some superiority to western medicine rehabilitation program on improving the neurological deficit and motor function. Kudiezi injection is safe and effective in the treatment of acute ischemic stroke.

keywords: Kudiezi injection acute ischemic stroke post-marketing re-evaluation

