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灯盏细辛注射液与灯盏生脉胶囊治疗缺血性中风上市后临床再评价

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中文摘要:目的: 验证灯盏细辛注射液和灯盏生脉胶囊(以下称灯盏组)上市后治疗缺血性中风的疗效和安全性。 方法 :采用多中心、前瞻性、实用性随机对照研究设计,应用"临床研究中央随机系统",对678例患者进行随机分组,灯盏组343例,西医组335例。灯盏组急性期以灯盏细辛注射液治疗为主,恢复期以口服灯盏生脉胶囊为主。疗效评价指标主要为随访360 d的重要临床结局事件(病死率、复发率、致残率、生存质量)。安全性评价主要观察实验室检查指标、不良事件及发生率。 结果 :随访360 d,灯盏组病死4例,病死率为1.17%,西医组病死16例,病死率为4.78%,灯盏组病死率显著低于西医组($P<0.05$);灯盏组复发11例,复发率为3.21%,西医组复发12例,复发率为3.59%, 灯盏组复发率略低于西医组;灯盏组致残率为39.53%,其中严重致残率为1.49%,西医组的致残率为40.13%,其中严重致残率为3.13%,灯盏组致残率与残疾严重程度均低于西医组;生存质量比较,灯盏组对脑卒中患者活动能力、上肢功能评分方面显著优于西医组($P<0.05$)。安全性分析显示,灯盏组发生不良事件11例,与药物治疗相关为4例,不良反应发生率1.17%,主要表现为发热寒战、皮疹、恶心、头晕心慌,全部为使用灯盏细辛注射液后出现,停药后1~2 d症状消失。灯盏组中发生13例肝功能异常,2例肾功能异常,临床医生判断3例ALT异常可能与药物使用有关,其余均与药物无关。 结论 :灯盏细辛注射液与灯盏生脉胶囊是治疗缺血性中风安全有效的中药。

中文关键词:灯盏细辛注射液 灯盏生脉胶囊 缺血性中风 上市后再评价

Post-marketed re-evaluation of fleabane injection and Dengzhan Shengmai capsule study on treatment in patients with ischemic stroke

Abstract: Objective : To verify the efficacy and safety of post-marketed fleabane injection combined with Dengzhan Shengmai capsules in the treatment of ischemic stroke (IS). Method : A multicentre, prospective, practical, randomized controlled study was carried out to compare the efficacy and safety of Dengzhan group (n=343) and western medicine group (n=335), appling "clinical study central stochastic system". The treatment of Dengzhan group is using fleabane injection in acute stage and Dengzhan Shengmai capsules in convalescence. The primary indexes of effect evaluation are the important outcome events in 360 days' follow-up, including mortality, recurrence, disability and quality of life to reflect the effect of clinical study. The indexes of safety evaluation involve laboratory examination results and incidence of adverse events. Result : After 360 days' follow-up, 4 people died of IS in Dengzhan group, and the mortality rate of which is 1.17%, while 16 died in Western medicine group (WM group), and the mortality rate is 4.78%, suggesting that the mortality rate of Dengzhan group is significantly lower than WM group ($P<0.05$). Eleven cases recurred in Dengzhan group, and the recurrence rate of which is 3.21%, while 12 recurred in WM group, and the recurrence rate is 3.59%, indicating that the recurrence rate of Dengzhan group is slightly lower than WM group. The disability rate of Dengzhan group is 39.53%, among which the rate of severely disabled cases are 1.49%, while the disability rate of WM group is 40.13%, among which the rate of severely disabled cases are 3.13%, suggesting that the disability rate of Dengzhan group is lower and the severity of disability is also lighter than WM group. In the field of quality of life, the activity ability and the upper limb function store of stroke patients in Dengzhan group improved far much better than WM group ($P<0.05$). Analysis of safety suggested that, adverse events occurred in 11 cases in Dengzhan group, among which 4 cases is related with the drug treatment, the incidence of adverse events of which is 1.17%, and the main manifestations involve fever and chilling, rash, nausea, dizziness, palpitation, etc. which were all appeared after the treatment of fleabane injection, and disappeared 1 to 2 days after drug withdrawal. 13 cases occurred abnormal liver

function and 2 cases abnormal kidney function in Dengzhan group. According to the judgment of clinical physicians, 3 case of ALT abnormality is possibly related to the treatment, the others are all unrelated with the treatment. Conclusion : Fleabane injection and Dengzhan Shengmai capsules are all safe and effective TCM in the treatment of ischemic stroke.

keywords:fleabane injection Dengzhan Shengmai capsule ischemic stroke post-marketing re-evaluation

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