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论文

HPLC-MS/MS法测定人体色甘酸钠血浆浓度及其药代动力学研究

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摘要：

采用HPLC-MS/MS法测定人血浆中色甘酸钠浓度，进行其滴鼻液和鼻用喷雾剂的药代动力学研究并评价其生物等效性。采用高效液相分离系统，流动相为乙酸铵-甲醇(含50%乙腈)(15∶85)，固定相为AGT Venusil XBP C_{18}(250 mm×4.6 mm ID， 5 μm)色谱柱。采用质谱检测系统， ESI离子源， 正离子模式， 多级反应监测(MRM)方式， *m/z* 469→263.1(色甘酸钠)， *m/z* 447.2→327.1(内标，普伐他汀钠)。在0.3～20 ng·mL^{-1}色甘酸钠血药浓度呈线性关系， 定量限为0.3 ng·mL^{-1}， 回收率在94.1%以上， 日内日间的RSD均小于14.3%。单剂量给药色甘酸钠鼻用喷雾剂或滴鼻液， 其药代动力学参数$T_{1/2}$分别为(1.82±0.54)和(1.59±0.52) h； T_{max}分别为(0.47±0.12)和(0.44±0.15) h； C_{max}分别为(9.79±4.66)和(10.88±4.05) ng·mL^{-1}， $AUC_{0-5\,h}$分别为(11.52±3.46)和(12.63±4.23) ng·mL^{-1}·h。色甘酸钠鼻用喷雾剂相对生物利用度F_r为(93.6±13.8)%。本法灵敏度高， 适用于色甘酸钠治疗药物监测及其药代动力学和生物利用度研究。

关键词： 色甘酸钠 HPLC-MS/MS 药代动力学 生物利用度

HPLC-MS/MS method for determination of sodium cromoglycate concentration in human plasma and its pharmacokinetics

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Abstract:

The study established an HPLC-MS/MS method for determining the concentrations of sodium cromoglycate in human plasma and evaluated the pharmacokinetics of nasal drops and nasal spray. A C_{18} column was used to separate sodium cromoglycate in plasma with a mobile phase of a mixture of ammonium-methanol (involves 50% acetonitrile) (15∶85) at a flow rate of 0.4 mL·min^{-1}. Electronic spray ionization (ESI) and multiple-reaction monitoring (MRM) were used for the determination of sodium cromoglycate in human plasma. The linear range of the standard curve of sodium cromoglycate was from 0.3 to 20 ng·mL^{-1}, and the minimum concentration of detection was 0.3 ng·mL^{-1}. The extraction recovery was more than 94.1%, intra-day and inter-day RSD were less than 14.3%. After a single dose of sodium cromoglycate, the main pharmacokinetic parameters of nasal spray and nasal drops were as follows, $T_{1/2}$ (1.82±0.54) h, (1.59±0.52) h; T_{max} (0.47±0.12) h, (0.44±0.15) h; C_{max} (9.79±4.66) ng·mL^{-1}, (10.88±4.05) ng·mL^{-1}; $AUC_{0-5\,h}$ (11.52±3.46) ng·mL^{-1}·h, (12.63±4.23) ng·mL^{-1}·h, F_r (93.6±13.8)%. The method is sensitive, rapid and accurate. It is suitable for therapeutic drug monitoring and human pharmacokinetic study of sodium cromoglycate.

Keywords: HPLC-MS/MS pharmacokinetics bioavailability sodium cromoglycate

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