

论文

中国健康志愿者口服福辛普利的药代动力学研究

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摘要:

目的 研究中国健康志愿者po福辛普利后的药代动力学。方法 10名男性健康受试者po福辛普利20 mg后,用LC/MS/MS法测定不同时间血浆中活性代谢物福辛普利拉浓度,SRM方式选择性检测待测物的特征碎片离子,full-scan ms²方式检测内标物的碎片离子。结果 本法线性良好,精密度、准确度、回收率均符合要求。测得的主要药代动力学参数为: T_{1/2}=(6.6±1.2) h, T_{max}=(3.7±1.1) h, C_{max}=(451.9±251.2) ng·mL⁻¹, AUC_{0-∞}=(3578.4±2231.2) h·ng·mL⁻¹。结论 本实验测得的T_{max}, C_{max}和AUC_{0-∞}均高于文献报道的白人受试者的参数值,而T_{1/2}显著低于文献值。

关键词: 福辛普利 福辛普利拉 LC/MS/MS法 药代动力学

PHARMACOKINETIC STUDY OF ORAL FOSINOPRIL IN HEALTHY CHINESE VOLUNTEERS

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Abstract:

AIM To determine the concentration of fosinoprilat in human plasma and study the pharmacokinetics of fosinopril in healthy Chinese male volunteers following a 20 mg oral dose. METHODS A liquid chromatographic-mass spectrometric assay has been developed for the determination of fosinoprilat in plasma of 10 healthy Chinese male subjects orally administered 20 mg fosinopril. Mobile phase: methanol-acetonitrile-0.1% ammonia water (30:30:40); Column: Hewlett Packard Zorbax C₈, 5 μm, 15 cm×4.6 mm ID; Flow rate: 0.2 ml.min⁻¹. Selected reaction monitoring(SRM) in mass spectrometric method has been used to detect the characteristic ion of fosinoprilat: m/z 434→m/z 237; internal standard substance enalapril was monitored by full-scan ms²: m/z 375→m/z 105~380. RESULTS Assay linearity was obtained in the range of 5.0~200.0 ng·mL⁻¹; Intra- and inter-day precisions were lower than 8.9% and 10.1%, respectively; relative error of the method was lower than 12%. Model-independent pharmacokinetic parameters of fosinoprilat were calculated using Topfit 2.0 software. The main pharmacokinetic parameters were: T_{1/2}=(6.6±1.2) h, T_{max}=(3.7±1.1) h, C_{max}=(451.9±251.2) ng·mL⁻¹, AUC_{0-∞}=(3578.4±2231.2) h·ng·mL⁻¹. The concentration-time curve of fosinoprilat after an oral dose of fosinopril was not fitted to one-, two- or three-compartment model. CONCLUSION The values of Tmax, Cmax and AUC_{0-∞} obtained here were much higher than those reported for Caucasian, but T_{1/2} was significantly lower than that reported. These results offered relevant information for rational use of fosinopril in Chinese subjects.

Keywords: fosinoprilat pharmacokinetics LC/MS/MS fosinopril

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