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论文

固相萃取结合HPLC-MS测定人血浆中奥曲肽的浓度及相对生物利用度固相萃取结合HPLC-MS测定人血浆中奥曲肽的浓度及相对生物利用度

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摘要：

目的建立人血浆中奥曲肽浓度的HPLC-MS测定法，研究国产奥曲肽注射剂的人体生物利用度。方法 血浆样品用HPL 1cc固相萃取小柱萃取，经Waters Xetrra C_{18} MS分离后测定。18名健康志愿受试者采用随机交叉试验设计，分别im奥曲肽试验制剂和参比制剂200 μg，不同时间点采血，比较两者的生物利用度。结果线性范围0.5～40 $\mu g \cdot L^{-1}$，方法回收率为97.1%～100.5%。日内、日间RSD分别为1.1%～1.6%，2.9%～4.8%。单剂量im奥曲肽200 μg后两种制剂的C_{max}分别为（19±10） $\mu g \cdot L^{-1}$和（19±11） $\mu g \cdot L^{-1}$，t_{max}分别为（0.50±0.15） h和（0.52±0.20） h；$AUC_{0\sim7h}$分别为（50±25） $h \cdot \mu g \cdot L^{-1}$和（50±25） $h \cdot \mu g \cdot L^{-1}$，$t_{1/2}$分别为(1.5±0.8) h 和(1.5±0.8) h。二者之间均无显著性差异，以进口奥曲肽为参比制剂，国产奥曲肽注射液的相对生物利用度为101%±10%。结论该方法灵敏、准确度高，可用于奥曲肽体内过程研究。两注射剂为生物等效性制剂。

关键词： 奥曲肽 固相萃取 高效液相色谱质谱联用 生物利用度

Determination of octreotide in human plasma by HPLC-MS with solid-phase extraction and study on the relative bioavailability of domestic and imported octreotide injections

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Abstract:

AimTo establish an HPLC-MS method for determination of octreotide in plasma and study the relative bioavailability of domestic and imported octreotide injections. MethodsOctreotide in plasma samples were extracted with a Waters solid-phase extraction mini column. HPLC-MS was carried out using a Waters Xetrra C_{18} column and a mobile phase consisting of CH_3OH-1% HAc (80∶20), the flow rate was 0.2 $mL \cdot min^{-1}$, and the internal standard was 6,7,4′-OH-isoflavone, the SIR ions for quantification were *m/z* 1 014.4 for octreotide and *m/z* 317.6 for internal standard. A single dose of 200 μg of domestic or imported preparations was intramuscularly given to 18 healthy volunteers in a randomized crossover study. Octreotide concentration in plasma was determined by LC-MS method. The pharmacokinetics and bioavailability were studied. ResultsThe regressive curve was linear (^{R}=0.999 7) within the range of 0.5-40 $\mu g \cdot L^{-1}$for octreotide. The pharmacokinetics parameters of domestic and imported injection were reply to one compartment model. The mean C_{max} were (19±10) $\mu g \cdot L^{-1}$ and (19±11) $\mu g \cdot L^{-1}$, t_{max} were (0.50±0.15) h and (0.52±0.20) h, $t_{1/2}$were (1.5±0.8) h and (1.5±0.8) h, AUC_{0-7h} were (50±25) $h \cdot \mu g \cdot L^{-1}$ and (50±25) $h \cdot \mu g \cdot L^{-1}$, respectively. The relative bioavailability of domestic to imported injection was 101%±10%. ConclusionThe method is accurat and sensible for assay of plasma octreotide concentration. The results of statistics showed the two preparations were bioequivalent.

Keywords: solid-phase extraction HPLC-MS bioavailability octreotide

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