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Pharmacokinetics and Safety of Methylergonovine Maleate Injection in Healthy Chinese Subjects

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SUMMARY. **The pharmacokinetics and safety of methylergonovine maleate (ME) injection (after single-dose intramuscular injection, i.m.) in 36 healthy Chinese female subjects were assessed in 0.1, 0.2, and 0.3 mg dose groups. Safety and tolerance were evaluated by monitoring adverse events and laboratory parameters, and pharmacokinetics was assessed by determining ME concentrations with a validated LC-MS/MS method. No serious adverse reactions occurred, and the pharmacokinetic parameters as AUC, C_{max}, $t_{1/2}$, and T_{max} of ME after 0.1, 0.2, and 0.3 mg injection were as follows: AUC 7.344 ± 1.154, 10.631 ± 2.718 L, and 15.405 ± 2.629 ng·h/mL; C_{max} 2.635 ± 0.479, 4.473 ± 1.663, and 6.260 ± 1.217 ng/mL; $t_{1/2}$ 2.068 ± 0.588, 2.287 ± 0.668, and 1.965 ± 0.508 h; T_{max} 0.641 ± 0.341, 0.483 ± 0.181, and 0.491 ± 0.207 h. ME injection is well tolerated and no serious adverse events occurred during the study. The mean C_{max} and AUC of ME are dose- proportional.**

RESUMEN. La farmacocinética y la seguridad de la inyección de maleato de metilergonovina (ME) (después de una inyección intramuscular de dosis única, i.m.) en 36 mujeres sanas chinas se evaluaron en grupos de dosis de 0,1, 0,2 y 0,3 mg. La seguridad y la tolerancia se evaluaron mediante la monitorización de eventos adversos y parámetros de laboratorio, y la farmacocinética se evaluó mediante la determinación de las concentraciones de ME con un método validado de LC-MS/MS. No se produjeron reacciones adversas graves, y los parámetros farmacocinéticos como AUC, C_{max}, $t_{1/2}$ y T_{max} de ME después de la inyección de 0.1, 0.2 y 0.3 mg fueron los siguientes: AUC 7.344 ± 1.154, 10.631 ± 2.718 y 15.405 ± 2.629 ng h/mL; C_{max} 2.635 ± 0.479, 4.473 ± 1.663 y 6.260 ± 1.217 ng/mL; t_{max} 2.068 ± 0.588, 2.287 ± 0.668 y 1.965 ± 0.508 h; T_{max} 0.641 ± 0.341, 0.483 ± 0.181 y 0.491 ± 0.207 h. La inyección de ME es bien tolerada y no se produjeron eventos adversos graves durante el estudio. Las medias de C_{max} y AUC de ME son proporcionales a la dosis.

KEY WORDS: healthy subject, methylergonovine, pharmacokinetics, safety, tolerance.

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