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Pharmacokinetics and pharmacodynamics of single-chain recombinant human follicle-stimulating hormone containing the human chorionic gonadotropin carboxyterminal peptide in the rhesus monkey.

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OBJECTIVE: To compare the pharmacokinetics of a long-acting FSH analog containing the hCG-beta carboxyterminal peptide (recombinant hFSH-CTP) with native recombinant hFSH and describe the pharmacodynamics of recombinant hFSH-CTP after SC injection in female rhesus monkeys. **DESIGN:** Rhesus monkey study. **SETTING:** Academic research environment. **ANIMAL(S):** Ten female rhesus monkeys. **INTERVENTION(S):** Recombinant hFSH and recombinant hFSH-CTP were administered via a single SC or IV dose to rhesus monkeys, and serial phlebotomy was performed (n = 2 and n = 4 for SC recombinant hFSH and recombinant hFSH-CTP, respectively; for IV dosing, n = 1 in each group). An additional two monkeys were pretreated with SC ganirelix and received SC recombinant hFSH-CTP after confirmation of pituitary suppression. **MAIN OUTCOME MEASURE(S):** Plasma disappearance rate of recombinant hFSH and recombinant hFSH-CTP and serum estradiol levels. **RESULT(S):** The elimination half-life of recombinant hFSH-CTP was twofold and fourfold longer than that for recombinant hFSH after SC and IV dosing, respectively. The absorption half-life was approximately threefold longer for recombinant hFSH-CTP than for recombinant hFSH after SC administration. Recombinant hFSH-CTP stimulates estradiol secretion for 5-7 days after an isolated SC dose. **CONCLUSION(S):** Addition of the hCG-beta carboxyterminal peptide to hFSH-beta results in an FSH analog with longer absorption and elimination half-lives compared with native hormone. This analog is capable of prolonged ovarian stimulation in rhesus monkeys after an isolated SC injection.