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## **Pharmacokinetics and pharmacodynamics of a new intranasal midazolam formulation in healthy volunteers.**

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We evaluated the pharmacokinetics and pharmacodynamics of single 5-mg doses of midazolam after administration of a novel intranasal (IN) formula, IM, and IV midazolam in an open-label, randomized, 3-way cross-over study in 12 healthy volunteers. IN doses were delivered as 0.1-mL unit-dose sprays of a novel formulation into both naris. Blood samples were taken serially from 0 to 12 h after each dose. Plasma midazolam concentrations were determined by liquid chromatography/mass spectrometry/mass spectrometry. Noncompartmental analysis was used to estimate pharmacokinetic parameters. The mean midazolam bioavailabilities and % coefficient of variation were 72.5 (12) and 93.4 (12) after the IN and IM doses, respectively. Median time to maximum concentration was 10 min for IN doses. Adverse events were minimal with all routes of administration, but nasopharyngeal irritation, eyes watering, and a bad taste were reported after IN doses. Our results support further development of this novel midazolam nasal spray.

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