# Pharmacokinetics of Scopolamine Intranasal gel Formulation (INSCOP) during Antiorthostatic Bedrest

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Space Motion Sickness (SMS) is experienced during early flight days of space missions and on reduced gravity simulation flights which require treatment with medications. Oral administration of scopolamine tablets is still a common practice to prevent SMS symptoms. Bioavailability of medications taken by mouth for SMS is often low and variable. Intranasal (IN) administration of medications has been reported to achieve higher and more reliable bioavailability than from an equivalent oral dose. In this FDA reviewed phase II clinical trial, we evaluated pharmacokinetics of an investigative new drug formulation, INSCOP during ambulatory (AMB) and antiorthostatic bedrest (HBR), a ground-based microgravity analog. Twelve subjects including 6 males and 6 females received 0.2 and 0.4 mg doses of INSCOP on separate days during AMB and ABR in a randomized, double blind cross over experimental design. Blood samples were collected at regular time intervals for 24 h post dose and analyzed for free scopolamine concentrations by an LC-MS-MS method. Pharmacokinetic parameters were calculated using concentration versus time data and compared between AMB and ABR conditions. Results indicated that maximum concentration and relative bioavailability increased marginally during ABR compared to AMB; differences in PK parameters between AMB and ABR were greater with 0.2 mg than with 0.4 mg dose. Gender specific differences in PK parameters was observed both during AMB and ABR with differences higher in females between the two conditions than in males. A significant observation is that while gender differences in PK appear to exist, the differences in primary PK parameters between AMB and ABR after IN administration, unlike oral administration, are minimal and may not be clinically significant for both genders.