ABSTRACT

Statement of Purpose, Innovation or Hypothesis: Space Motion sickness (SMS) is a long-standing problem for astronauts on both short and long duration space flights. Scopolamine (SCOP) is frequently used for the treatment of motion sickness (MS), and is available as transdermal patch and patch dosage forms. These formulations of SCOP are ineffective for the treatment of SMS. Intranasal dosage forms are noninvasive with rapid absorption and enhanced bioavailability, thus allowing precise and reduced dosing in addition to offering rescue and treatment options. An oral, injectable and transdermal formulations of SCOP are not very effective in space due to poor bioavailability.

Description of Methods and Materials: The present clinical trial compares PK and bioavailability of INSCOP in 12 normal, healthy subjects (6 male & 6 female) during ambulation (AMB) and antioorthostatic bed rest (ABR) used as a ground-based microgravity analog. Subjects received 0.2 mg and 0.4 mg doses of INSCOP during AMB and ABR in a 4-way crossover design.

Data and Results: Results indicated no difference between AMB and ABR in PK and bioavailability of INSCOP in 12 normal, healthy subjects (6 male & 6 female) during ambulation (AMB) and antioorthostatic bed rest (ABR) used as a ground-based microgravity analog. Subjects received 0.2 mg and 0.4 mg doses of INSCOP during AMB and ABR in a 4-way crossover design.

RESULTS

The plasma concentration time profiles were analyzed using the non-compartmental method. After administration of the 0.2mg dose of INSCOP during AMB and ABR, the AUC values were similar with no significant difference at 95% CI. However, AUC values were significantly different after 0.4mg dose. All relevant PK parameter estimates are listed in Table 1.

The parameters were evaluated for bioequivalence between AMB and ABR. Results of this evaluation (table 2) showed that the two doses are not bioequivalent with limits between 80 and 125%. The table shows that the two doses are not bioequivalent with limits between 80 and 125%.

CONCLUSIONS

After intranasal administration of scopolamine to human subjects during AMB and ABR conditions PK parameters were similar at the low dose (0.2 mg), but not at the high dose (0.4 mg) between the two conditions. Comparison of Cmax and AUC values suggest that treatments between the two conditions were not bioequivalent when the 90% confidence intervals fall outside the specified limits of 80 and 125% for both doses tested.

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