Motion sickness (MS) 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 tablet dosage forms. These formulations of SCOP are ineffective for the treatment of SMS. Intrasinal 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 intranasal gel dosage formulation of scopolamine (INSOP) was developed and pharmacokinetics (PK) and bioavailability were determined in clinical trials with human subjects under IND guidelines.

**INTRODUCTION**

Motion sickness (MS) is a long-standing problem for space travelers on short and long duration space flight. Oral antiemetics are not very effective in space due to poor bioavailability.

Scopolamine (SCOP) is the most frequently used drug by recreational travelers, with patches and tablets currently available on the market. Common side effects of antiemetics, in general, include drowsiness, sedation, dry mouth and reduced psychomotor performance. Severity and persistence of side effects are often dose related. Side effects can be detrimental in high-performance demanding settings, such as space flight, military.

Oral, injectable and transdermal formulations of SCOP are either invasive, unsuitable or ineffective for the treatment of space motion sickness. The intranasal dosage form of scopolamine offers great promise for the treatment of MS on Earth and in space:

- It is noninvasive
- Rapid absorption facilitates rescue and treatment options with the same formulation
- Enhanced and reliable bioavailability allows precise and reduced dosing options

**METHODS**

**Data Analysis**

Pharmacokinetic parameters were calculated from the plasma concentration-time data by non-compartmental methods using WinNonLin standard edition, version 5.2. The peak plasma concentration (Cmax) and time to peak concentration (Tmax) were determined directly from the plasma profiles. The elimination rate constant (Kₑ) was calculated from the slope of the terminal phase of the plasma concentration-time plot. The area under the curve (AUC(∞)) was estimated by the linear trapezoidal method with extrapolation to infinity based on the concentration of the last time point measured divided by the terminal rate constant.

Bioequivalence of the two doses between control and ABR was determined at 90% CI using mean Cmax, AUC(0-t) and AUC(0-∞) with limits between 80.00% and 125.00%.

**RESULTS**

The plasma concentration time profiles were analyzed using the non-compartmental method. After administration of the 0.2mg dose of INSOP during AMB and ABR, AUC values were similar with no significant difference at 95% CI. However, AUC values suggest that treatments between the two conditions were not bioequivalent 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 fell outside the specified limits of 80 and 125% for both doses tested.

**CONCLUSIONS**

After intranasal administration of scopolamine to human subjects during AMB and ABR conditions PK parameters were similar at 90% CI. However, Cmax values suggest that treatments between the two conditions were not bioequivalent when the 90% confidence intervals fell outside the specified limits of 80 and 125% for both doses tested.

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