

Efficacy of Intranasal Scopolamine HBr (INSCOP, DPI-386) for the prevention of vomiting or the need for rescue medication associated with motion.



BACKGROUND

Nausea vomiting associated with motion remains a significant problem affecting Warfighter performance in the modern military. This is true regardless of mode of transportation. Unlike symptoms associated with motion in civilian populations, military personnel often do not have the ability to withdraw from the offending stimulus.

The development of symptoms associated with motion, particularly GI symptoms such as nausea and vomiting have been treated with medications including antihistamines and anticholinergic medications such as scopolamine. Scopolamine has been shown to be the most effective means of preventing the symptoms associated with motion.

To date, transdermal scopolamine patch has been the most common delivery system for the treatment of symptoms associated with motion using scopolamine.

- Oral scopolamine has a very poor bioavailability, and the use of oral medications in a patient population suffering from severe nausea and vomiting has impracticalities.
- Intranasal scopolamine HBr (INSCOP, DPI-386) has been studied as an alternative delivery of scopolamine which allows for rapid vascular uptake and potentially direct absorption into the central nervous system.

APPROACH



¹A formulation of scopolamine has been developed using a viscous gel for an intranasal delivery system. Previous studies have demonstrated a reduced incidence of patient reported “motion sickness” and a lower incidence of self-reported nausea compared to patients receiving transdermal scopolamine or placebo when exposed to 3 days of ocean-going boat rides.

² Further study was required by the FDA to determine the efficacy of this formulation in the reduction of the incidence of nausea and vomiting or the need for rescue medication associated with motion.

References:

- ¹DPI-386-MS-21 - A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of the Safety and Efficacy of DPI-386 Nasal Gel on Ocean going Vessels for the Prevention and Treatment of Nausea Associated with Motion Sickness.)
- ² DPI-386-MS-33 - A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of the Efficacy and Safety of DPI-386 Nasal Gel for the Prevention of Nausea and Vomiting Associated with Motion).

SOLUTION

A Phase 3 randomized, double-blind, placebo-controlled study was performed on 503 subjects who had been screened for experiences with motion sickness in the past (Motion Sickness Susceptibility Questionnaire Short-Form (MSSQ Short)). Subjects were dosed with intranasal scopolamine (0.2mg) or placebo (Gel with no scopolamine). Subjects were then exposed to open sea conditions. Subjects were divided into 8 separate voyages with varying sea conditions. The primary efficacy endpoint was the proportion of subjects who reported no vomiting and no use of rescue medication (e.g., antihistamine) within 4 hours after receiving study drug or to the end of the voyage.

FINDINGS

Subjects receiving intranasal scopolamine demonstrated a significantly lower incidence of vomiting or the need for rescue medication in comparison to individuals administered placebo ($p < .0001$).

No serious or unexpected adverse events were seen in either the scopolamine treated or placebo groups. The incidence of moderate to severe nausea was significantly less in the intranasal scopolamine group than in the placebo group ($p < .0001$).

