



A Multi-Center Study to Determine
The Safety and Efficacy of
Trutek's "Multi Acting Nasal Particle Blocker (MAPB)"
as a Preventive Treatment for Cold and Flu

Clinical Study Report

07 March 2012

CLINICAL STUDY REPORT

STUDY ID:	TTK-MAPB-MN01
SPONSOR:	Trutek Corp. 281 East Main Street Somerville, NJ 08876 United States of America Tel.: +1 908 685 1111
INVESTIGATIONAL DEVICE:	Multi Acting Nasal Particle Blocker
Study Initiation Date (First Subject Enrolled):	02 August 2011
Study Completion Date (Last Subject Completed):	12 November 2011
Name & Contact Details of Sponsor's Signatory:	Vir Narula Chief Operating Officer Trutek Corp. 281 East Main Street Somerville, NJ 08876 United States of America Tel.: +1 908 685 1111
Report Date:	7 March 2012

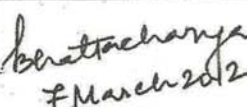
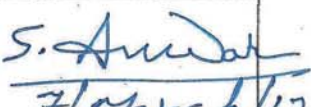
Confidentiality Statement

This study was performed in compliance with Good Clinical Practices, including the archiving of essential documents. The information presented in this document may be unpublished material and should be treated as the confidential property of Trutek Corp. No unpublished information contained herein may be disclosed without prior written approval from Trutek Corp.

2 SYNOPSIS

Name of Company: Trutek Corp.		<i>(For National Authority Use only)</i>
Name of Product: Multi Acting Nasal Particle Blocker (MAPB) gel		
Title of the Study:	A Randomized, Prospective, Open label, Parallel group, Comparative, Multi-Center Study to Determine the Safety and Efficacy of Trutek's device "Multi Acting Nasal Particle Blocker (MAPB)" as a Preventive Treatment for Cold and/or Flu.	
Investigators:	The list of Investigators is presented in Appendix 3.	
Investigation Sites:	Three sites, one in Gurgaon and two in Jaipur, in India were selected for this study.	
Study Period:	Date of first subject enrolled: 02 August 2011 Date of last subject completed: 12 November 2011	
Objectives:	<p>The primary objective of the study was:</p> <ul style="list-style-type: none"> To evaluate the efficacy of MAPB nasal application gel in the prevention of the common cold and/or flu <p>The secondary objective was:</p> <ul style="list-style-type: none"> To evaluate the safety of MAPB nasal application gel in the prevention of the common cold and/or flu 	
Methodology:	<p>Randomized, prospective, open label, parallel group, comparative, multi-center study with two groups</p> <p>Group A: Active treatment with MAPB gel</p> <p>Group B: No treatment control group</p>	
Total Number of Subjects:	Planned: 600 healthy subjects (300 subjects each in Group A and Group B)	Randomized: 600 healthy subjects (300 subjects each in Group A and Group B)
Evaluated:	Efficacy: 600 healthy subjects (300 subjects each in Group A and Group B)	Safety: 600 healthy subjects (300 subjects each in Group A and Group B)
Diagnosis and Criteria for Inclusion:	<p>Subjects who fulfilled the following criteria were considered for enrollment into the study:</p> <ol style="list-style-type: none"> Male or female from 18 years to 70 years of age. Willing to sign written informed consent form. Willingness to comply with the test procedure. 	
Investigational Device:	Multi Acting Nasal Particle Blocker manufactured by Trutek Corp. is a patent pending topical gel that filters airborne particles from entering the nasal passages.	
Duration of Administration:	MAPB gel was recommended to be applied 4 to 6 times per day for 8 weeks as directed in the package insert.	
Duration of Treatment:	The study period was for approximately 8 weeks (57 days) with a total of 2 visits, on Day 0 and Day 57, to the investigation site and 3 intermediate phone calls with the Investigator.	

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Reference Therapy:	Control group (Group B) was given no treatment.	
Primary Endpoint:	The primary study endpoint was: <ul style="list-style-type: none">Percentage of subjects that were cold and/or flu free in the treatment group at the end of study as compared to the subjects who were cold and/or flu free in the no treatment group	
Secondary Endpoints:	The secondary study endpoints were: <ul style="list-style-type: none">Incidence of treatment related adverse events	
Statistical Methods:	Sample Size Calculation <p>The sample size calculation was based on the detection of difference between two proportions.</p> <p>Assuming the cold and/or flu free subject rates in no treatment group (Group B) and MAPB treatment group (Group A) as 85% and 94%, respectively, detecting a difference of 9% with 95% confidence (two sided 5% level of significance) and with 90% power would require 264 subjects approximately in each group. Adjusting for anticipated 11% dropout rate and balanced randomization, a total of 594 subjects in 1:1 ratio were to be enrolled in the study. The chi-square test for proportions with continuity correction was used for these calculations.</p> <p>The descriptive statistics for continuous variables was presented with number (n) of non-missing observations, mean, standard deviation, median, minimum, and maximum. For categorical data, descriptive statistics was presented with number of exposed subjects, and number (n) with percentage of observations in the various categories of the endpoint, where percentage was based on the exposed subjects. Statistical significance was declared if the two-sided probability value was ≤ 0.05.</p> <p>For efficacy analysis, logistic regression model with treatment group as independent factor was used to compare the subjects at the end of the study. The variables, which can have influence on the cold and/or flu, were taken into consideration by using these factors in logistic regression analysis. P-values, odds ratios and corresponding 95% confidence intervals were reported. Additionally, chi-square test/Fisher exact test (small expected frequency) was used to compare the ‘treatment’ and the ‘no treatment’ groups at 5% level of significance.</p>	
Summary of Efficacy Results:	<ul style="list-style-type: none">Statistically significant higher number of subjects with cold and/or flu free status was observed in Group A than Group B at the end of the study on Day 57The probability of cold and/or flu was approximately 3 times higher in Group B than Group A	
Summary of Safety Results:	<ul style="list-style-type: none">No Serious Adverse Device Effects (SADEs) or Serious Adverse Events (SAEs) were observed or reported in the studyTwo subjects reported Adverse Device Effects (ADEs) where one reported mild sneezing and another reported vomiting. As per sole discretion of the Investigator, these Adverse Events (AEs) were	

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	<p>considered to have probable and possible relationships to treatment, respectively</p> <ul style="list-style-type: none"> In both the cases there was no recurrence of the event. Hence, the subjects continued to apply MAPB gel and went on to complete the study unhindered for total study duration of 8 weeks 		
Conclusions:	<p>Six hundred healthy subjects were enrolled in this prospective, open label, parallel group, comparative, multi-center study and were randomized 1:1 to either MAPB or no treatment group. The objective of the study was to evaluate the efficacy and safety of MAPB gel in prevention of cold and/or flu. Three hundred subjects randomized to Group A were instructed to apply MAPB gel 4 to 6 times a day for a period of 8 weeks and the remaining 300 subjects randomized to Group B were not given any treatment and served as the control group.</p> <p>At the end of study (8 weeks), 295/300 (98.3%) subjects using MAPB gel were cold and/or flu free; whereas 285/300 (95%) subjects not on any treatment were cold and/or flu-free. This difference was of statistical as well as of clinical significance. Subjects of Group B had 3 times higher probability of getting cold and/or flu than subjects of Group A.</p> <p>In terms of safety, none of the subjects reported any SAEs or SADEs. Two subjects in Group A reported ADE where one had sneezing and another subject had vomiting. Both the ADEs were of mild intensity. As per sole discretion of the Investigator, these ADEs were considered to have probable and possible relationships to treatment, respectively. There was no recurrence of the event in both the subjects. Hence, both of them continued to apply MAPB gel and went on to complete the study unhindered for total study duration of 8 weeks.</p> <p>In conclusion, MAPB nasal application gel was considered as an efficacious and safe gel in prevention of common cold and/or flu in healthy subjects.</p>		
MNI Signatures	 07-MAR-2012 Shekar Sunkoju, Biostatistician, Max Neeman International	 7 March 2012 Priyanka Bhattacharya Medical Writer, Max Neeman International	 7 March 2012 Dr. Shariq Anwar Director, Operations Max Neeman International
Date of Report:	07 March 2012		