



In Vivo Performance Study Summary ViaNase™ electronic atomizer

Title: Performance of ViaNase™ in the administration of insulin and placebo in the treatment of elderly patients presenting with Alzheimer's disease and Amnesic Mild Cognitive Impairment

Overview

ViaNase intranasally delivered insulin or placebo to patients (n=24) with Alzheimer's Disease (AD) or Amnesic Mild Cognitive Impairment (MCI). Patients ranged in age from 65-95 years. Nine were female and fifteen were male. In some cases, the patient was assisted by a caregiver during the treatment.

Principal investigation site

Veterans Administration Seattle and Tacoma, WA in conjunction with University of Washington, Seattle, WA

Principal investigator

Suzanne Craft, PhD

Methods

The duration of the trial was 6 months (October 2005 – March 2006). Each dose was 0.20 ml (20IU) of insulin or placebo. Duration of each dose was 2 minutes. Total number of doses was 1,008. All treatments were performed in the patient's home.

Performance of ViaNase Electronic Atomizer

Failure rate of the ViaNase was 0.00%. There was no statistically significant variation in the performance parameters of ViaNase post-study when compared to the pre-study specifications.

Droplet size variation (MMAD) pre and post-study	DV(10)=+6.9%	DV(50)=+0.6%	DV(90)=+16.7%
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Atomization rate variation Pre- and post-study	-4.7%
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Results of Patient Satisfaction Study

A post-trial study survey was conducted using a 4 point scale: 1=very difficult, 2=somewhat difficult, 3=somewhat easy, and 4=very easy.

1. How did you find the nasal spray device to use?	3.59
2. How easy did you find ViaNase to hold during the treatment?	3.65
3. How did the nose piece fit the bottom of your nose?	3.55
4. Did you experience liquid dripping down from your nostrils while using ViaNase?	67% no 33% yes
5. Did you experience any of the following while using ViaNase?	
a. Stinging in nostrils?	0%
b. Burning in nostrils?	0%
c. Shortness of breath?	0%
d. Sensation of medication being delivered to your nose?	5%
e. Pain?	0%
f. Other? Sneezing	14%
g. None of the above.	77%
6. Did you experience any sense of smelling of the study drug during the treatment?	77% no 23% slight odor
7. Did you experience any taste of the study drug with the treatment?	95% no 5% slight taste

Feedback from the Principal Investigator

“The ViaNase electronic atomizer performed flawlessly during the duration of the clinical trial period. Elderly patients and their caregivers found the device easy to use, comfortable to hold, and extremely reliable. I am excited about the possibilities of this type of intranasal delivery device to deliver a wide range of formulations.”

- Suzanne Craft, PhD

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Conclusion

The ViaNase electronic atomizer had a failure rate of 0.00% during a 6-month clinical trial in the study on the delivery of insulin or placebo in 24 patients with AD and MCI.

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