

## New smoking cessation therapy proves promising

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A novel technology for delivering nicotine to the lungs may soon give smokers a new way to kick the habit.

When compared to the nicotine vapor delivery system used in the Nicotrol/Nicorette inhaler, the new technology proved more effective at delivering nicotine to the blood stream. As a result, it provides immediate relief of withdrawal symptoms, according to Duke University Medical Center researchers. Users also reported the new nicotine delivery method was more tolerable than the current inhaler because it caused less throat irritation.

"We wanted to replicate the experience of smoking without incurring the dangers associated with cigarettes, and we wanted to do so more effectively than the nicotine replacement therapies currently on the market," said Jed Rose, Ph.D., director of the Duke Center for Nicotine and Smoking Cessation Research where the technology is being developed. He presented the data today at the Society for Nicotine and Tobacco Research (SRNT) in Baltimore, MD.

The Nicotrol inhaler is a <u>smoking cessation</u> therapy that delivers nicotine vapor to the mouth and upper airways, but little of it reaches the lungs.

Duke's new technology employs a unique method to deliver nicotine to the lungs. In today's presentation, the researchers show the new lung delivery technology results in rapid absorption of nicotine that provides immediate relief of withdrawal symptoms and also re-creates some of



the familiar sensations that are pleasurable to smokers.

Current methods that deliver medicine to the lungs -- metered dose sprays, dry powder inhalers or nebulizers that create a fine mist - do not replicate the natural inhalation used by smokers when drawing on a cigarette. And, because medication residue often deposits in the mouth and throat, doses aren't always high enough to ensure the appropriate amount reaches the lungs.

Duke's new technology combines the vapor phase of pyruvic acid, which occurs naturally in the body, and nicotine. "When the two vapors combine, they form a salt called nicotine pyruvate," explains Rose. "This reaction transforms invisible gas vapors into a cloud of microscopic particles which is inhaled, just like a smoker inhales from a cigarette."

In a study of the new Duke technology, nine healthy smokers inhaled 10 puffs of nicotine pyruvate in increasing doses, 10 puffs from a Nicotrol/Nicorette inhaler cartridge, and 10 puffs of room air (placebo). Blood was drawn before and after each set of inhalations. When the results were analyzed, the Duke researchers noted rapid increases in plasma nicotine concentrations following the nicotine pyruvate inhalations and less complaints of harshness/irritation when compared to the Nicotrol/Nicorette control cartridge. The smokers also said their cravings for cigarettes were substantially alleviated following the nicotine pyruvate inhalations.

"Compared to the current nicotine vapor inhaler, we are able to give smokers more <u>nicotine</u>, although still less than a cigarette, with less irritation, resulting in reduced cravings," said Rose. "Thus we are able to achieve a therapeutic effect with greater tolerability."

More research is needed to examine the safety and effectiveness of prolonged use of the inhalation system, and to assess its role in helping



people quit smoking. But, Rose says if all goes well, he anticipates the product could become commercially available within three to five years.

He also says the novel inhalation system may one day prove useful for delivery of other medications. Duke has filed patent applications on the new technology, which was invented by Rose and his colleagues, including his brother, Seth D. Rose, Ph.D., Duke colleague, Thangaraju Murugesan, Ph.D., and James E. Turner, an inventor of the Nicotrol/Nicorette inhaler.

## Provided by Duke University

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