

# The Pharmacokinetics, Efficacy, Safety, and Ease of Use of a Novel Portable Metered-Dose Cannabis Inhaler in Patients With Chronic Neuropathic Pain: A Phase 1a Study, Journal of Pain and Palliative Care Pharmacotherapy, Informa Healthcare

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## REPORT

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Elon Eisenberg, MD, is Director, Pain Relief Unit, Rambam Medical Centre, and Associate Professor of Neurology, Rappaport Faculty of Medicine, The Technion-Israel Institute of Technology, Haifa, Israel. Miri Ogintz, RN, is with the Institute of Pain Medicine and Department of Internal Medicine, Rambam Medical Centre. Shlomo Almog, PhD, is with the Department of Physiology and Pharmacology, Sackler School of Medicine, Tel-Aviv University, and the Institute of Pharmacology and Toxicology, Chaim Sheba Medical Center, Tel-Hashomer, Israel.

Address correspondence to: Elon Eisenberg, MD, Pain Research Unit, Institute of Pain Medicine, Rambam Health Care Campus, Haifa 31096, Israel (E-mail: ).

## ABSTRACT

Chronic neuropathic pain is often refractory to standard pharmacological treatments. Although growing evidence supports the use of inhaled cannabis for neuropathic pain, the lack of standard inhaled dosing plays a major obstacle in cannabis becoming a “main stream” pharmacological treatment for neuropathic pain. The objective of this study was to explore the pharmacokinetics, safety, tolerability, efficacy, and ease of use of a novel portable thermal-metered-dose inhaler (tMDI) for cannabis in a cohort of eight patients suffering from chronic neuropathic pain and on a stable analgesic regimen including medicinal cannabis. In a single-dose, open-label study, patients inhaled a single  $15.1 \pm 0.1$  mg dose of cannabis using the Syqe Inhaler device. Blood samples for  $\Delta^9$ -tetrahydrocannabinol (THC) and 11-hydroxy- $\Delta^9$ -THC were taken at baseline and up to 120 minutes. Pain intensity (0–10 VAS), adverse events, and satisfaction score were monitored following the inhalation. A uniform pharmacokinetic profile was exhibited across all participants ( $\Delta^9$ -THC plasma  $C_{\max} \pm SD$  was  $38 \pm 10$  ng/mL,  $T_{\max} \pm SD$  was  $3 \pm 1$  minutes,  $AUC_{0 \rightarrow \infty} \pm SD$  was  $607 \pm 200$  ng·min/mL). Higher plasma  $C_{\max}$  increase per mg  $\Delta^9$ -THC administered (12.3 ng/mL/mg THC) and lower interindividual variability of  $C_{\max}$  (25.3%), compared with reported alternative modes of THC delivery, were measured. A significant 45% reduction in pain intensity was noted 20 minutes post inhalation ( $P = .001$ ), turning back to baseline within 90 minutes. Tolerable, lightheadedness, lasting 15–30 minutes and requiring no intervention, was the only reported adverse event. This trial suggests the potential use of the Syqe Inhaler device as a smokeless delivery system of medicinal cannabis, producing a  $\Delta^9$ -THC pharmacokinetic profile with low interindividual variation of  $C_{\max}$ , achieving pharmaceutical standards for inhaled drugs.