

**A Physician-Initiated Multiple-Dose, Single Period,
Phase 0-I Dose Ranging Study to Examine
Leveller™ HypoSpray Human Insulin Adult
Healthy Volunteer Patients**

Protocol No.: LEV 101-D-022521
ClinicalTrials.gov Reference NCT04857320

Criteria for evaluation: Statistical Analysis Plan

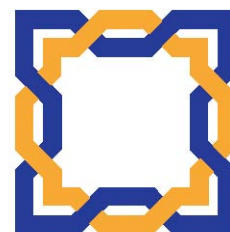
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Version 1.3

SPONSOR: Langford Research Institute

Principal Investigator: William D. Kirsh, D.O., M.P.H.

Approved by Langford Research Institutional Review Board April 21st, 2021



AMENDMENTS:

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<p>Criteria for evaluation: Statistical Analysis Plan</p>	<p>Pharmacokinetics</p> <p><i>Primary pharmacokinetic variables</i></p> <p>The primary pharmacokinetic variables include: the reduction of serum glucose from baseline and at typical post prandial spikes and the amount of insulin necessary to accomplish this reduction.</p> <p>In addition to 90% confidence intervals, the data will be summarized by medians, and maximum and minimum values.</p> <p>The elimination half-life of Insulin will be compared using non-transformed data and parametric techniques.</p> <p>Averages for the serum glucose and Post-prandial excursions will be compared against averages for experimental periods.</p>
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