

# Pharmacokinetics and Safety Assessment of L-Tetrahydropalmatine in Cocaine Users: A Randomized, Double-blind, Placebo Controlled Study

Hazem E. Hassan, and Deanna Kelly

**Table S1. Medication Side Effects in Adult Male Cocaine Users**

	L-THP (N=12*)	Placebo (N=11**)
Diarrhea	1	0
Cough	1	0
Nasal Congestion	1	0
Headache	2	3
Nausea	1	1
Stiffness	1	0
Malaise	1	2
Contact dermatitis	1	0
Loss of Appetite	1	1
Sedation	1	4
Sneezing	1	1
Dizziness	1	3
Restlessness	3	1
Sore throat	2	0
Fatigue	1	0
Tinnitus	1	0
Constipation	1	0
Toothache	1	0
Dry mouth	0	3
Euphoria	0	1
Excess salivation	0	2
Itching	0	1
Insomnia	0	1
Lower back pain	0	1

\* includes one participant who contributed two sets of data; once as a non-completer withdrawn on Day 3 and once as a completer

\*\* Subject X was not included in the analysis as this subject discontinued on Day 1

**Table S2. Vital Signs and ECG QTcB intervals in 20 Adult Cocaine-Using Men following intranasal cocaine (40 mg) administration to subjects pretreated with L-THP or Placebo**

	<b>L-THP (N=10)</b>	<b>Placebo (N=10)</b>	<b>p-value</b>
<b>Systolic Blood Pressure (mmHg)</b>			
Baseline	124.0 ± 11.6	120.7 ± 15.8	
Maximum change from baseline	17.1 ± 10.8	22.3 ± 12.1	0.32
<b>Diastolic Blood Pressure (mmHg)</b>			
Baseline	69.5 ± 9.6	73.0 ± 5.5	
Maximum change from baseline	11.0 ± 6.6	9.5 ± 6.2	0.60
<b>Heart Rate (bpm)</b>			
Baseline	72.2 ± 6.9	78.6 ± 15.3	
Maximum change from baseline	10.5 ± 11.4	11.9 ± 8.5	0.76
<b>QTcB interval (msec)</b>			
Baseline	408.6 ± 21.3	418.7 ± 19.1	
Maximum change from baseline	19.1 ± 15.6	13.4 ± 9.5	0.34

Subjects received 3.5 days of L-THP (30 mg po bid) or placebo and cocaine challenge on morning of the 4<sup>th</sup> day

QTcB = QTc interval with Bazett's correction