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Supplementary Material

Article Title: The SNAP 101 Double-Blind, Placebo/Active-Controlled, Safety, Pharmacokinetic, and Pharmacodynamic Study of INP105 (Nasal Olanzapine) in Healthy Adults

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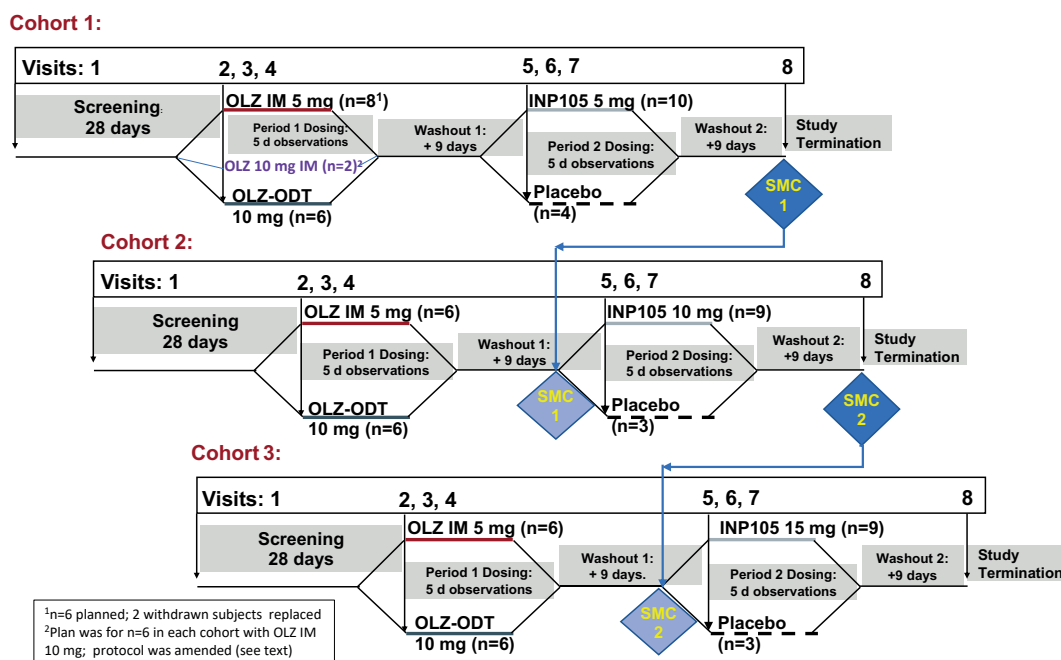
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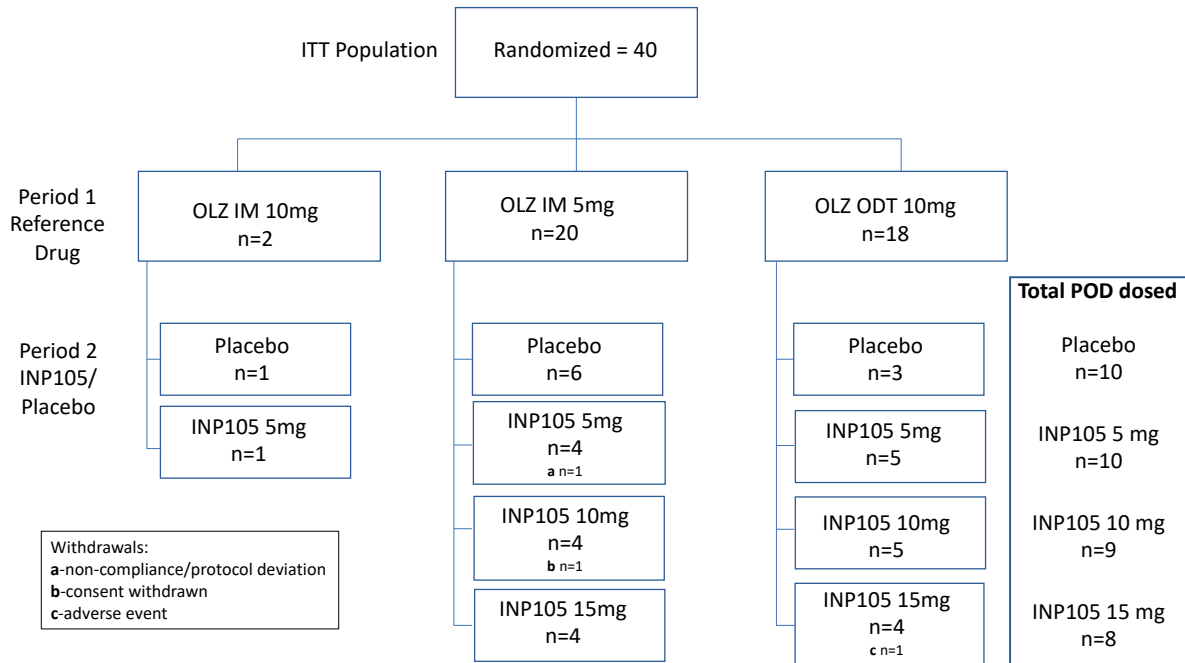
Data Supplement

Article Title: SNAP 101: Double-Blind, Placebo/Active-Controlled, Safety, Pharmacokinetic (PK), and Pharmacodynamic (PD) Study of INP105 (nasal olanzapine) in Healthy Adults

Supplementary Figure 1. Study Design



Supplementary Figure 2. Subject Disposition



Supplementary Table 1. Baseline demographic characteristics

Period 1	OLZ IM 5 mg	OLZ IM 5 mg	OLZ IM 5 mg	OLZ IM 5 mg	OLZ IM 10 mg	OLZ IM 10 mg	OLZ ODT 10 mg
Period 2	INP105 5 mg	INP105 10 mg	INP105 15 mg	Placebo	INP105 5 mg	Placebo	INP105 5 mg
	(n=5)	(n=5)	(n=4)	(n=6)	(n=1)	9n=1)	(n=5)
Age, years ^a	26.4 ± 4.9	25.8 ± 3.0	26.5 ± 4.5	26.2 ± 3.9	24.0	25.0	32.0 ± 12.4
Female, n (%)	3 (60.0)	1 (20.0)	2 (50.0)	4 (66.7)	1 (100.0)	0	3 (60.0)
Race, n (%)							
White	4 (80.0)	3 (60.0)	3 (75.0)	3 (50.0)	0	1 (100.0)	4 (80.0)
Asian	0	1 (20.0)	1 (25.0)	2 (33.3)	0	0	0
Other	1 (20.0)	1 (20.0)	0	1 (16.7)	1 (100.0)	0	1 (20.0)
Weight, kg ^a	78.6 ± 14.9	76.7 ± 14.6	76.5 ± 8.3	71.2 ± 18.0	67.6	84.0	73.9 ± 13.1
BMI, kg/m ² ^a	26.3 ± 3.8	23.8 ± 4.4	26.3 ± 1.3	24.1 ± 2.1	23.7	26.8	25.2 ± 3.6

Period 1	OLZ ODT 10 mg	OLZ ODT 10 mg	OLZ ODT 10 mg	Overall
Period 2	INP105 10 mg	INP105 15 mg	Placebo	
	(n=5)	(n=5)	(n=3)	(n=40)
Age, years ^a	25.6 ± 5.1	27.6 ± 5.9	33.7 ± 12.5	27.5 ± 6.7
Female, n (%)	3 (60.0)	1 (20.0)	2 (66.7)	20 (50.0)
Race, n (%)				
White	4 (80.0)	3 (60.0)	3 (100.0)	28 (70.0)
Asian	1 (20.0)	2 (40.0)	0	7 (17.5)
Other	0	0	0	5 (12.5)
Weight, kg ^a	73.4 ± 11.4	76.8 ± 17.9	64.4 ± 9.0	74.4 ± 13.3
BMI, kg/m ² ^a	23.9 ± 1.9	24.3 ± 3.9	24.0 ± 3.9	24.7 ± 3.0

^a Mean ± standard deviation; BMI – body mass index

Supplementary Appendix 1

Agitation/Calmness Evaluation Scale

The following is an example ACES test. Further details on test to be used will be provided in a Procedures Manual.

Subject ID: _____

Study Time Point: _____

Date and Time of Assessment: _____

Please answer the following by putting a mark in the box to indicate how the subject appears with respect to his/her level of agitation/calmness.

Self-Assessed Level of Agitation/Calmness

Current State (please choose one)		Select
1	Marked Agitation	
2	Moderate Agitation	
3	Mild Agitation	
4	Normal	
5	Mild Calmness	
6	Moderate Calmness	
7	Marked Calmness	
8	Deep Sleep	
9	Unable to be Aroused	

Based on Battaglia J, Lindborg SR, Alaka K, et al. Calming versus sedative effects of intramuscular olanzapine in agitated patients (see Appendix). *Am J Emerg Med.* 2003;21(3):192–198.

Supplementary Appendix 2

Visual Analogue Scale

The following is an example VAS test. Further details on test to be used will be provided in a Procedures Manual.

Subject ID: _____

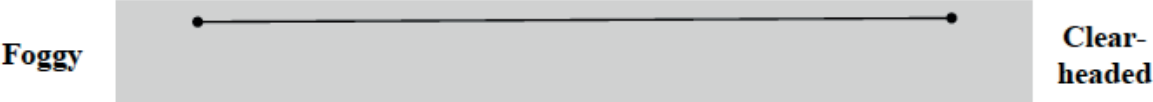
Study Time Point: _____

Date and Time of Assessment: _____

Please answer the following question by putting a mark on line to indicate intensity of response to the items in question.

Self-Assessed Level of Sedation

1. How strong is your current level of sedation?



Based on Bond A, Lader M. The use of analogue scales in rating subjective feelings. *Br J Med Psychol.* 1974;47:211–218.