NIDA Clinical Trials Network

0068Z (ENR)

Web Version: 1.0; 1.04; 05-22-18

Date of assessment:*(STARTDT)* _____ *(mm/dd/yyyy)*

Inclusion Criteria

In order to meet eligibility ALL Inclusion answers must be "Yes".

1.	Participant is 18 to 65 years of age:*(R4PTAGE)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
2.	Participant is interested in reducing or stopping methamphetamine use:*(R4METSTP)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
3.	Participant is able to speak English sufficiently to understand the study procedures and provide written informed consent to participate in the study:*(R4ENGLSH)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
4.	Participant meets DSM-5 criteria for moderate or severe methamphetamine use disorder (4 or more criteria):*(R4METDSM)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
5.	Participant self-reported methamphetamine use on 18 or more days in the 30 day period prior to consent using the Timeline Followback (TLFB):*(R4METDAY)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
6.	Participant provided at least 2 urine samples positive for methamphetamine out of a possible 3 tests within a 10 day period during which clinic visits occurred with at least 2 days between visits:*(R4METUDS)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
7.	Participant is female and agrees to use acceptable birth control methods and have periodic urine pregnancy testing done during participation in the study unless documentation of hysterectomy provided:*(R4BCUSE)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	☐ 96-Not applicable
8.	Participant meets subjective and objective measures of being opioid-free prior to naltrexone induction per study medical clinician's determination:*(R4OPFREE)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
9.	Participant is willing to comply with all study procedures and medication instructions: *(R4COMPLY)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
10.	Participant agrees to use a smartphone app (downloaded for free to own device or on a study provided smartphone device) to take daily videos of medication dosing: *(R4VIDEO)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	

Exclusion Criteria

In order to meet eligibility ALL Exclusion answers must be "No".

1.	Participant has an acute medical or psychiatric disorder that would, in the judgment of the study medical clinician, make participation difficult or unsafe:*(R4PSYCH)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
2.	Participant has suicidal or homicidal ideation that requires immediate attention: *(R4SUICDE)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
3.	Participant has a history of epilepsy, seizure disorder, or head trauma with neurological sequelae (e.g., loss of consciousness that required hospitalization); current anorexia nervosa or bulimia; or any other conditions that increase seizure risk in the opinion of the study medical clinician:*(R4SEIZUR)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
4.	Participant has evidence of second or third degree heart block, atrial fibrillation, atrial flutter, prolongation of the QTc, or any other finding on the screening ECG that, in the opinion of the study medical clinician, would preclude safe participation in the study: *(R4BLOCK)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
5.	Participant has Stage 2 hypertension as determined by study medical clinician (e.g., greater than or equal to 160/100 in 2 out of 3 readings during screening):*(R4HYPTEN)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
6.	Participant has any elevated bilirubin test value per laboratory criteria OR any liver function test (LFT) value > 5 times the upper limit of normal as per laboratory criteria: *(R4LIVER)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
7.	Participant has platelet count <100x10^3/µL:*(R4PLATE)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
8.	Participant has a body habitus that precludes gluteal intramuscular injection of XR-NTX in accordance with the administration equipment (needle) and procedures:*(R4HABTUS)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
9.	Participant has a known allergy or sensitivity to bupropion, naloxone, naltrexone, PLG (polyactide-co-glycolide), carboxymethylcellulose, or any other component of the XR-NTX diluents:*(R4ALERGY)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
10.	Participant has been in a prior study of pharmacological or behavioral treatment for methamphetamine use disorder within 6 months of study consent:*(R4STUDY)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
11.	Participant has taken an investigational drug in another study within 30 days of study consent:*(R4INDDRU)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
12.	Participant has been prescribed and taken naltrexone or bupropion within 30 days of consent:*(R4PRESCR)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
13.	Participant is currently enrolled in formal behavioral or pharmacological addiction treatment services:*(R4ADDCTX)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
14.	Participant is receiving ongoing treatment with tricyclic antidepressants, xanthines (i.e., theophylline and aminophylline), systemic corticosteroids, nelfinavir, efavirenz, chlorpromazine, MAOIs, central nervous system stimulants (e.g., Adderall, Ritalin, etc.), or any medication that, in the judgment of the study medical clinician, could interact adversely with study medications:*(R4TREAT)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
15.	Participant has a current pattern of alcohol, benzodiazepine, or other sedative hypnotic use which would preclude safe participation in the study as determined by the study medical clinician:*(R4SEDATE)*	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	
16.	Participant requires treatment with opioid-containing medications (e.g., opioid	☐ 0-No	☐ 1-Yes	☐ 97-Unknown	

analgesics) during the study period:*(R4OPMED)*

17. Participant has a surgery planned or scheduled during the study period:*(R4SURGRY)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
18. Participant is currently in jail, prison or any inpatient overnight facility as required by court of law or has pending legal action or other situation (e.g., unstable living arrangements) that could prevent participation in the study or in any study activities: *(R4PRISON)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
19. Participant is female and currently pregnant, breastfeeding, or planning on conception: *(R4PREGNT)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown ☐ 96-Not applicable

Eligibility for Randomization

1. Is the participant eligible for the study?*(R4ELGSTY)* ☐ 0-No ☐ 1-Yes
2. Will the participant be enrolled?*(R4ELGRDM)* ☐ 0-No ☐ 1-Yes

If "No", specify:*(R4NORSP)*

2-Declined study participation
3-Death
4-Judgement of site/research staff
5-Failed to return to clinic prior to enrollment
99-Other

If "Judgement of site/research staff" or "Other", specify:*(R4JGOTSP)*

Comments:*(R4COMM)*