Transdermal Rotigotine as Adjunct to Behavioral Therapy for Cocaine Use Disorder

Status: RECRUITING

Eligibility Criteria

Age: 25 years to 70 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Male or female subjects between 25 and 70 years of age. * Meet current DSM-5 criteria for Cocaine Use Disorder (CocUD), moderate or severe * Able to understand and comply with study procedures * Have positive urine result for cocaine metabolite benzoylecgonine (BE) during at least one screening visit (out of up to three visits, depending on participants' preference) AND/OR self-report of recent cocaine use (approximately past 30 days). * Have hematology and chemistry laboratory tests that are within normal limits, except that liver function tests must be no more than 2x of the upper limit of normal (if any elevation is above the limit

•must be judged by the study physician to be clinically insignificant). * No clinically significant abnormalities on baseline ECG. * Be able to demonstrate an understanding of study procedures and follow instructions including behavioral laboratory and fMRI testing. * Women must either be unable to conceive (i.e., surgically sterilized, sterile, or postmenopausal) or be using a reliable form of contraception (e.g., abstinence, birth control pills, intrauterine device with spermicide, or condoms). Men will be advised to use condoms. All females must provide negative pregnancy urine tests before study entry, at each visit during the study, and the end of study participation. * Body Mass Index (BMI) between 18-45kg/M2 and weight of at least 50kg at screening

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Exclusion Criteria:

* Have concurrent secondary DSM-5 diagnosis of any psychoactive substance use disorder other than cocaine, alcohol, methamphetamine, nicotine, opioid, or marijuana use disorder. * Have a DSM-5 axis I psychiatric disorder other than substance use disorder, including but not limited to Bipolar I Disorder, Schizophrenia, or other psychotic disorder that require treatment with antipsychotics, or a neurological disorder requiring ongoing treatment and/or making study participation unsafe. Comorbid PTSD, Generalized Anxiety Disorder and Major Depressive Disorder will be allowed. * Consistent and regular (as opposed to intermittent, infrequent, or as needed) use of medications contraindicated for concurrent use along with RTG, or would confound the mechanism of RTG action and data interpretation. These include DA antagonists such as antipsychotic medications (especially neuroleptics) or metoclopramide. * Subjects with evidence or history of any clinically significant medical disorder including biliary obstruction, clinically significant hepatic disease, severe cardiovascular or pulmonary disease, bronchial asthma, renal, or endocrine disease. However, controlled hypertension, controlled hypothyroidism, and cancer in remission over 5 years will not be excluded. * Have a history of seizures (excluding childhood febrile seizures) or loss of consciousness (e.g. from traumatic brain injury) for more than 30 minutes. * Have significant current suicidal or homicidal ideation or a suicide attempt within the past 6 months, based on the Columbia Suicide Severity Rating Scale (C-SSRS). * Be HIV positive by self-report or history. * Be pregnant or nursing or not using a reliable form of contraception if able to conceive. All females must provide negative pregnancy urine tests before study entry, at each visit during the study, and the end of study participation * Have any other illness, or condition, which in the opinion of the clinical co-investigator (Arias) would preclude safe and/or successful completion of the study. * Be allergic to rotigotine. * Have taken any investigational drug within 45 days prior to baseline * Demonstrate intolerance to, poor adherence to, or extreme skin irritation by daily application of known placebo "practice" skin patches during the screening phase * Current/pending criminal charges that may result in incarceration within the next 60 days * Self-report of allergic or other reactions to sulfites (e.g. in foods)

Conditions & Interventions

Interventions:
DRUG: Rotigotine Transdermal System [Neupro], DRUG: Placebo
Conditions:
Substance-Related Disorders

More Information

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Principal Investigator:
Phase: PHASE2
IRB
Number:
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