Phase Ib/2a Drug-drug Interaction Study of a Combination of 45mg Dextromethorphan With 105 mg Bupropion

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 65 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Males and female subjects between 18

•65 years of age; * Understand the study procedures and provide written informed consent in the English language. * Meet current DSM-5 criteria for OUD, of at least moderate severity, currently engaged in MOUD treatment at a buprenorphine-naloxone sublingual film total daily dose ranging from 8mg/2mg to 24mg/6mg or buprenorphine sublingual tablet 5.7mg/1.4mg to 17.1/4.3 daily for at least 2 weeks at screening. Or on a stable dose of depot injectable buprenorphine for at least four months, with at least one week since last depot buprenorphine injection. * Have a positive urine drug screen for buprenorphine during screening and upon presenting for the first laboratory day on the clinical research unit to document buprenorphine use; * Quick Inventory of Depressive Symptomatology (16-Item) (QIDS-SR16) score of mild or greater (\>6) * Females must be non-pregnant and non-lactating. Additionally, for females with childbearing potential (ie., have not undergone sterilization via hysterectomy, bilateral tubal ligation, or bilateral oophorectomy, or at least 1 year post-menopausal), participants must agree to use an acceptable form of contraception during study participation and to continue its use for at least 30 days after the last dose of the study drug (e.g, abstinence, intrauterine device, hormonal implant, hormonal patch/ring/pill, condoms (male or female).

Exclusion Criteria:

* Contraindications for participation as determined by medical history and physical exam performed by study NP or study physician; * Pregnant or nursing women; * Baseline ECG with clinically significant abnormal conduction; * Uncontrolled serious psychiatric or major medical disorder; including uncontrolled hypertension, seizure disorder, anorexia nervosa or bulimia, bipolar disorder, schizoaffective disorder, or schizophrenia; * Taking antidepressant medications (tricyclic antidepressants, SSRIs, SNRIs, MAOIs), antibiotic linezolid, antiepileptics, or CNS stimulants (amphetamine, methylphenidate) within the two weeks prior to initiation of study medication * History of adverse reaction or allergy to dextromethorphan or bupropion * Current severe alcohol use disorder or current benzodiazepine use or recent (within last 3 months) discontinuation of alcohol with severe alcohol use disorder or discontinuation of benzodiazepines with severe benzodiazepine use disorder * Current DSM-5 diagnosis of any psychoactive substance use disorder other than opioids, cocaine, marijuana, or nicotine, or mild or moderate alcohol use disorder. Diagnosis of mild to moderate use disorder for alcohol will not be considered exclusionary. * Significant current suicidal or homicidal ideation (C-SSRS "yes" answers on questions 4 or 5) or a history of suicide attempt within the past 6 months. * Any other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the subject inappropriate for entry into this study.

Conditions & Interventions

Interventions:
DRUG: Placebo, DRUG: Auvelity
Conditions:
Addiction, Opioid Use, Substance Use Disorders, Opioid Use Disorder

More Information

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