Safety and Tolerability Study of VVZ-2471 in Healthy Volunteers

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 65 years old

This study is also accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria Participants must meet all of the following criteria to be eligible for the study: 1. Demographics: Male or female, between 18 and 65 years of age. 2. High Impulsivity: Must demonstrate high impulsivity during the screening period, defined as an Immediate Memory Task (IMT) Commission Error by Correct Deletions (CE/CD) ratio \> 0.25. 3. Informed Consent: Able to understand study procedures, follow instructions, and provide written informed consent in the English language. 4. Health Status: Be in generally good health based on medical history, physical exam, clinical laboratory values, vital signs, and ECG done during the screening period, as deemed by the Principal Investigator (PI) or designee. 5. Vital Signs (Resting): Resting pulse between 55 and 95 bpm; Systolic Blood Pressure between 90-120 mmHg; Diastolic Blood Pressure between 50-80 mmHg. 6. Vital Signs (Orthostatic): A set of orthostatic vital signs completed during screening and on each study visit demonstrating a decrease in Systolic Blood Pressure\< 20 mmHg and Diastolic Blood Pressure \<10 mmHg upon standing. 7. BMI: Body Mass Index between 18.5 and 35 kg/m². 8. Toxicology: Urine drug test negative for non-prescribed substances and a breath (or oral fluid) alcohol screen negative during screening. 9. Cardiac Safety: QTcF interval \< 450 ms and ECG findings considered normal or not clinically significant at screening by the PI/designee. 10. Laboratory Values: Clinical labs completed during screening must meet the following safety thresholds: * Serum creatinine, AST, ALT, BUN: \< 1.5 x Upper Limit of Normal (ULN) * Platelet count: \>140 x 10^9/L * INR: \< 1.2 * PT/aPTT: \< 1.2 x ULN * Fibrinogen: \> 175 mg/dL 11. Female Participants: Must not be of childbearing potential. They must be either post-menopausal or surgically sterile. They must not be pregnant or breastfeeding. 12. Male Participants: Male subjects of reproductive potential must use a highly effective contraceptive method from first dose through 90 days after the last dose and to refrain from sperm donation during the same period. Exclusion Criteria Participants meeting any of the following criteria will be excluded: Psychiatric \& Substance Use 1. Psychosis and bipolar disorder: Any lifetime history of psychosis or bipolar disorder. 2. Current Psychiatric Disorder: Current or recent (within the last year) DSM-5 diagnosis of any other psychiatric disorder that would make study participation unsafe, including but not limited to depressive disorders, trauma- or stress related disorders, and anxiety disorders that in the opinion of the investigator would make study participation unsafe. 3. Substance Use Disorder: Current DSM-5 diagnosis (any severity) of an alcohol or drug use disorder, or use of illicit/non-prescribed substances within the last 12 months. o Note: Tobacco use disorder is not considered exclusionary. 4. Suicidality: Current or recent suicidal or homicidal ideation (C-SSRS "yes" answers on any questions) or a history of suicide attempt within the past 12 months. Medical \& Neurological 5. Neurological Disorders: History of neurological disorders including epilepsy or a family history of epilepsy, intractable/complicated migraine syndromes, cluster headache syndrome, extrapyramidal/pyramidal disorders, cerebrovascular, or degenerative disorders. 6. Seizure History: Any lifetime history of seizure. 7. Traumatic Brain Injury (TBI): Lifetime history of brain injury with loss of consciousness \> 30 minutes, Past-year brain injury with loss of consciousness \< 30 minutes. 8. Cardiovascular Conditions: History of heart failure, cardiomyopathy, sick sinus syndrome, second or third-degree AV block, myocardial infarction, pulmonary congestion, symptomatic/significant cardiac arrhythmia, or clinically significant abnormal conduction on baseline ECG. 9. Bleeding \& Coagulation: Recent history (within 6 months) of clinically significant bleeding; or history of intracranial hemorrhage, subdural/epidural hematoma, hemorrhagic stroke, AVM, or bleeding diatheses. 10. Systemic Disease: History of malignancy (cancer), or significant respiratory, gastrointestinal, renal, urological, reproductive, endocrine, dermatological, or metabolic disorders.11. Liver/Pancreas: Pancreatic or liver disease that currently requires medical treatment. 12\. Positive HIV, HCV or HBC test results indicative of HIV infection or active hepatitis B or hepatitis C infection. Medications \& Interactions 13. CYP3A4 Interactions: Currently taking prescription/OTC drugs or supplements known to significantly inhibit CYP3A4 (e.g., clarithromycin, ketoconazole, ritonavir, grapefruit juice) or induce CYP3A4 (e.g., phenobarbital, rifampicin, St. John's Wort). 14\. CNS Active Medications: Currently taking a 5-HT2AR or mGluR5 antagonist or other CNS active medications that may increase risk as deemed by the PI or designee (e.g., antidepressants, antipsychotics, mood stabilizers, anticonvulsants, opioids, CGRP antagonists, triptans, ergotamines, or anxiolytics). 15\. Study Drug History: Any previous medically adverse reaction to a 5-HT2AR or mGluR5 antagonist. 16\. Concurrent Trials: Participation in another clinical trial with study medication administration within 30 days prior to first dosing. Other 17. General Safety: Any current, uncontrolled clinically significant medical condition that would make study participation unsafe, as deemed by the PI or designee.

Conditions & Interventions

Interventions:

DRUG: Placebo pills for 14-day intervention, DRUG: VVZ-2471 for 14-day intervention

Conditions:

Healthy Controls

More Information

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Principal Investigator:

IRB

Number:

System ID: NCT07531316