Repurposing Semaglutide for the Treatment of Cocaine Use Disorder

NCT07227948

Status	RECRUITING
Phase	Phase 2
Sponsor	The University of Texas Health Science Center, Houston
Enrollment	75 participants

Key Eligibility Criteria

Inclusion (6)

- Ability to provide informed consent before any study-related activity, willing to comply with all study procedures, and be available for the duration of the study.
- Meet Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM 5) diagnostic criteria for CUD and report recent cocaine use (verified by at least one positive urine drug screen (UDS) for the cocaine metabolite benzoylecgonine (BE), during intake).
- Have body mass index (BMI) of e25 kg/m2
- Agree (if the participant is female and of child-bearing potential) to use effective contraceptive methods, unless the participant's male partner(s) is surgically sterile (underwent vasectomy). Acceptable contraceptives include oral contraceptives, contraceptive sponge, patch, double barrier (diaphragm/spermicidal or condom/spermicidal), intrauterine contraceptive system, etonogestrel implant, medroxyprogesterone acetate contraceptive injection, complete abstinence from sexual intercourse, and/or hormonal vaginal ring. Contraceptive measures sold for emergency use after unprotected sex are not acceptable methods for routine use. Women of child-bearing potential must provide negative urine pregnancy test prior to randomization. Note: A woman is considered fertile (of childbearing potential) following menarche and until becoming postmenopausal unless permanently sterile. Women in the following categories are not considered a woman of childbearing potential: premenarcheal, premenopausal female with one of the following: documented hysterectomy, documented bilateral salpingectomy, documented bilateral oophorectomy. Postmenopausal female is defined as no menses for 12 months without an alternative medical cause. Females on HRT and whose menopausal status is in doubt will be required to use one of the nonhormonal highly effective contraception methods if they wish to continue their hormone replacement therapy (HRT) during the trial.
- Have a medical and psychiatric history and a brief physical examination demonstrating no clinically significant contraindications for study participation, in the judgment of the Study Physician and the Principal Investigator.

... and 1 more (see full listing online)

Exclusion (32)

- Medical Exclusions
- Personal or first-degree relative(s) history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN 2).
- History or presence of chronic pancreatitis or recent acute pancreatitis.
- Type 1 or type 2 diabetes mellitus (previously diagnosed or indicated by HbA1C e48 mol/mol (6.5%) as measured at screening).
- Severe gastrointestinal disease (i.e., severe gastroparesis).

... and 27 more (see full listing online)

Locations (1 total)

The University of Texas Health Science Center at Houston, Houston, Texas, United States