Exablate for LIFU Neuromodulation in Patients With Opioid Use Disorder (OUD) and/or Other Substance Use Disorders (SUDs)

NCT04197921

Status	RECRUITING
Phase	Not Applicable
Sponsor	InSightec
Enrollment	29 participants

Key Eligibility Criteria

Inclusion (9)

- Males and non-pregnant females, age 18 - 60 years old
- Subject meets DSM-5 criteria for OUD and/or other SUDs including alcohol (assessed via the SCID-5) of at least two years duration
- Subject is currently receiving outpatient treatment from the WVU Comprehensive Opioid Addiction Treatment Program (COAT), Intensive Outpatient Program (IOP) or any other program which implements the COAT model; residential or inpatient treatment from the WVU Center for Hope and Healing or an affiliated WVU hospital; or receiving outpatient/inpatient/residential treatment from similar programs that are well known to the research team. If the subject is prescribed medication for AUD or OUD (e.g. buprenorphine-naloxone, naltrexone), they will be on a stable dose of the medication for the 7 days prior to the procedure. Stable is defined as within the therapeutic range but does not require same exact dose for 7 days.
- Subject has been off opioids and other illicit substances, except for cannabis, confirmed via urine toxicology screen
- The NAc is apparent on MRI such that treatment targeting can be performed directly (visible on MRI) and indirectly (using other anatomical structures for measurements)

... and 4 more (see full listing online)

Exclusion (36)

- Subjects who are taking medications which may adversely interact with MOUD (See Appendix B for full list). Being on one of these medications would not automatically exclude a participant from study participation, does not automatically exclude a prospective subject from study participation. If a prospective or current subject is taking any medication listed in Appendix B, the study investigator is responsible for determining whether the subject is eligible for inclusion or continued study participation."
- Subject with standard contraindications for MR imaging such as non-MRI compatible implanted metallic devices
- Subject with known intolerance or allergies to the MRI contrast agent gadolinium (GADOVIST®)
- Subject who are unable or unwilling to tolerate the required prolonged stationary position during treatment (approximately 2-3 hours)
- More than 30% of the skull area traversed by the sonication pathway is covered by scars, scalp disorders (e.g., eczema), or atrophy of the scalp

... and 31 more (see full listing online)

Locations (4 total)

Tampa General Hospital, Tampa, Florida, United States
University of Maryland, Baltimore, Baltimore, Maryland, United States
Weill Cornell Medicine, New York, New York, United States
... and 1 more locations