Effects of Intranasal Oxytocin in Patients With Arginine-vasopressin Deficiency

NCT04789148

Status	RECRUITING
Phase	Phase 1
Sponsor	Elizabeth Austen Lawson
Enrollment	40 participants

Plain Language Summary

This study is testing whether a nasal spray form of oxytocin (sometimes called the "bonding hormone") can improve quality of life and emotional well-being in people with arginine-vasopressin deficiency — a hormone disorder also known as central diabetes insipidus or cranial diabetes insipidus, where the body does not produce enough of a key hormone that regulates water balance.

You may be eligible if...
- You are 18 or older
- You have a confirmed diagnosis of arginine-vasopressin deficiency
- Your thyroid function and blood sodium levels are normal
- Your hormone replacement therapy has been stable

You may NOT be eligible if...
- You have had an active substance use disorder in the past 6 months
- You have a history of psychosis
- You have had active suicidal thoughts or plans in the past month
- You have recently changed any medications (within 4 weeks)

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (5)

- Age 18 and above
- Arginine-vasopressin deficiency
- Normal FT4 or T4
- Normal serum/plasma sodium
- Stable hormone replacement

Exclusion (11)

- Active substance use disorder within the last 6 months
- History of psychosis
- Suicidal behavior and/or active suicidal ideation with plan and/or intent, e.g., suicidal ideation of type 4 or type 5 as assessed by the Columbia Suicide Severity Rating Scale (C-SSRS), in the last month
- Medication changes within 4 weeks of enrollment or planned medication changes during the study
- History of chronic nasal obstruction or local pathology in nostril pathway which, in the opinion of the investigator, would prevent appropriate nasal administration of the study drug.

... and 6 more (see full listing online)

https://clinicaltrials.gov/study/NCT04789148

Locations (1 total)

Massachusetts General Hospital, Neuroendocrine Unit, Boston, Massachusetts, United States