

Safety and Effectiveness of Valbenazine as Adjunct Therapy to Botulinum Toxin Injections in Cervical Dystonia

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Idiopathic CD (neck musculature first and most prominently affected) * 18-75 years old (participants excluded if their dystonia symptoms began before age 18 as childhood-onset dystonia typically represents a genetic and/or primary generalized form of dystonia) * Onset of dystonia ≥ 18 years old, no known hyperkinetic movement disorder-related genetic mutation * Dystonia severity more than minimal and not very severe as defined by Toronto Western Spasmodic Torticollis Rating Scale-2 Motor Severity (TWSTRS-2-Severity) score ≥ 5 and ≤ 20 . * Stable on botulinum toxin injections last 90 days (BoNT dose change $\leq 10\%$ and patient reported stability of response over last two injection cycles) * Stable on other neuroactive medications.

Exclusion Criteria:

* History of deep brain stimulation * History of uncontrolled or untreated depression in the prior 3 months, suicidality, or history of suicide attempts * History of uncontrolled liver disease or failure * History of tardive dyskinesia or tardive dystonia * Currently taking dopaminergic and/or anti-dopaminergic medications including VMAT2 inhibitors or other antipsychotic medications * Exposure to dopaminergic and/or anti-dopaminergic medications including VMAT2 inhibitors or other antipsychotic medications in the last 30 days -Presence of parkinsonism or other movement disorder other than dystonia on exam -Receiving botulinum toxin injections at a planned frequency other than every 3 months or typically receive injections at intervals ≤ 11 weeks or ≥ 13 weeks -Known history of long QT syndrome or cardiac tachyarrhythmia or any clinically significant cardiac abnormality. * Prolonged QTc as defined by ≥ 450 msec for men and ≥ 470 msec for women

Conditions & Interventions

Interventions:

DRUG: Valbenazine, DRUG: Placebo

Conditions:

Cervical Dystonia

More Information

Contact(s): Ananna Zaman - Ananna.Zaman@vcuhealth.org

Principal Investigator:

Phase: PHASE2

IRB

Number:

System ID: NCT06771323

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