MDC Clinical Trials: Updated as of 3/17/2022

Contents

1) **Title:** Web-Based Automated Imaging Differentiation of Parkinsonism (AID-P)

- **Sponsor:** University of Florida
- **PI:** David Simon
- **Coordinator:** Hannah Babcock, hbabcock@bidmc.harvard.edu, 617-667-9890
- **Main goal:** test a novel machine-learning software as a non-invasive means of differentiating between different Parkinsonian syndromes early in disease
- **Study population:** Ages 40-80
  - **PD:** symptom duration of 5-9 years; H&Y stage 2 or 3 on medication at baseline
  - **MSA:** possible or probable diagnosis
  - **PSP:** possible or probable diagnosis
- **Key study criteria:** Must be able to undergo an MRI
- **Study duration:** up to 18 months—2 visits total
- **Current study status:**
  - **ACTIVE, ENROLLING MSA & PSP**
  - **ENROLLMENT CLOSED FOR PD**

2) **Title:** A Phase 3, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Flexible-Dose, 27-Week Trial to Evaluate the Efficacy, Safety, and Tolerability of Tavapadon as Adjunctive Therapy for Parkinson's Disease in Levodopa-Treated Adults With Motor Fluctuations (TEMPO-3 Trial)

- **Sponsor:** Cerevel Therapeutics, LLC
- **PI:** Sam Frank
- **Coordinator:** Hannah Babcock, hbabcock@bidmc.harvard.edu, 617-667-9890
- **Main goal:** to assess the effect of tavapadon (as adjunctive therapy for PD in L-dopa treated subjects) on the change from baseline in total daily hours of "ON" time without troublesome dyskinesia in subjects who are experiencing motor fluctuations
- **Study population:** Subjects with good responses to L-dopa who are experiencing motor fluctuations and at least 2.5 hours "OFF" time each day
- **Key study criteria:**
  - Ages 40-80
  - Minimum 2.5 hours "OFF" time on at least 2 consecutive days
  - Good response to Levodopa: at least 4 doses/day and 400 mg/day
- **Study duration:** 35 weeks total; 27 weeks of treatment
  - 58-week Open Label Enrollment period following study completion

- **Drug administration:** 1:1 randomization to either Tavapadon ranging from 5-15 mg (titrated according to individual subject tolerability) or Placebo, oral, once per day
- **Current study status: ACTIVE, ENROLLING**

3) Title: A Phase 3, Double-blind, Randomized, Placebo-Controlled, Parallel-group, 27-week Trial to Evaluate the Efficacy, Safety, and Tolerability of Two Fixed Doses of Tavapadon in Early Parkinson's Disease (Tempo-1 Trial)

- **Sponsor:** Cerevel Therapeutics, LLC
- **PI:** Sam Frank
- **Coordinator:** Hannah Babcock, hbabcock@bidmc.harvard.edu, 617-667-9890
- **Main goal:** testing the efficacy and risk/benefit profile of tavapadon, a partial agonist of the dopamine D1-like receptors, in 2 fixed doses in subjects with early PD
- **Study population:** early PD patients who require pharmacologic intervention for disease management
- **Key study criteria:**
    - Ages 40-80
    - Within 3 years of PD diagnosis
    - H&Y stage 1, 1.5, or 2
    - Treatment naïve to dopaminergic agents
    - Prior and concurrent use of MAO-B inhibitors is permitted if use was initiated >90 days before participation, and if the dosage will remain stable for the duration of the trial
- **Study duration:** 35 weeks total; 27 weeks of treatment
    - 58-week Open Label Enrollment period following study completion
- **Drug administration:** either 5 mg tavapadon, 15 mg tavapadon, or matching placebo administered orally (via a tablet) once daily for up to 27 weeks

4) **Title:** Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of 36 Weeks of Treatment with NLY01 in Early-stage Parkinson's Disease (NLY01-PD-1)

- **Sponsor:** Neuraly, Inc.
- **PI:** David Simon
- **Coordinator:** Áine Russell, arussel2@bidmc.harvard.edu, 617-667-9885
- **Main goal:** testing if NLY01, an exenatide analogue, will slow the clinical progression of PD
- **Study population:** early de novo PD patients
- **Key study criteria**
    - Age 30-80 years old
    - Within 3 years of PD diagnosis
    - Not on any PD medications (including amantadine, rasagiline, and trihexyphenidyl)
    - Not likely to require dopaminergic treatment during the duration of the study
- **Study duration:** 12 months; 36 weeks of treatment
- **Drug administration:** Study material will be given as a weekly subcutaneous injection of 2.5 mg or 5 mg NLY01, or matching placebo
- **Current study status: ENROLLMENT CLOSED**

5) **Title:** A multicenter, randomized, active-controlled, double-blind, double-dummy, parallel group clinical trial, investigating the efficacy, safety, and tolerability of continuous subcutaneous ND0612 infusion in comparison to oral IR-LD/CD in subjects with Parkinson's disease experiencing motor fluctuations (BouNDless)

- **Sponsor:** NeuroDerm Ltd.
- **PI:** Lan Luo
- **Coordinator:** Hannah Babcock, hbabcock@bidmc.harvard.edu, 617-667-9890
- **Main goal:** testing the effect of continuous subcutaneous ND0612 infusion on daily "ON" time without troublesome dyskinesia
- **Study population:** Advanced PD patients experiencing motor fluctuations; advanced patients considering DBS
- **Key study criteria**
    - At least 30 years old
    - Diagnosis of PD
    - Experiencing motor fluctuations on an average of at least 2.5 hours daily
    - On at least 4 doses/day and 400 mg/day of levodopa
- **Study duration:** 96 weeks maximum; 24 weeks of treatment with an optional 5 year open-label extension
- **Drug administration:** Study material will be self-administered as a daily subcutaneous injection of ND0612, or matching placebo
- **NOTE:** 11 out of 19 study visits can be made virtual
- **Current study status: ACTIVE, ENROLLING**

6) **Title:** A Dose Selection Trial of Light Therapy for Impaired Sleep in Parkinson's Disease (NeuroNEXT)

- **Sponsor:** National Institute of Neurological Disorders and Stroke (NINDS)
- **PI:** Lan Luo
- **Coordinator:** Hilda Gutierrez, hgutier1@bidmc.harvard.edu
- **Main goal:** testing if once- or twice-daily bright-white light therapy will improve sleep in PD patients
- **Study population:** patients with PD and co-existing sleep disruption
- **Key study criteria**
    - Diagnosis of PD
    - Hoehn & Yahr stage 2-4
    - Mild, moderate, or severe difficulty going to sleep or staying asleep throughout the night (indicated by a score >2 on the Sleep Problems question of MDS-UPDRS part 1)
    - Stable dose of all PD medications for at least 30 days prior to randomization
    - Willing to wear an actiwatch and complete daily sleep logs
    - No use of hypno-sedative drugs for sleep or stimulants
- **Study duration:** 16 weeks
- **Drug administration:** 8 weeks of one hour of full-spectrum white light either once per day, twice per day, or once per week
- Potential study participants using hypno-sedative drugs for sleep or stimulants will be allowed to taper these drugs, and will become eligible for participation 30 days after the taper is complete
- **Current study status: ACTIVE, ENROLLING**

7) Title: A Randomized Placebo-controlled Trial of Zoledronic Acid for Prevention of Fractures in Patients with Parkinson's Disease (Trial of Parkinson's and Zoledronic Acid) (TOPAZ)

- **Sponsor:** National Institute of Aging, Parkinson's Foundation, PSG
- **PI:** David Simon
- **Coordinator:** Áine Russell, arussel2@bidmc.harvard.edu, 617-667-9885
- **Main goal:** testing if study drug will reduce the risk of clinical fractures among individuals with PD or neurodegenerative parkinsonism
- **Study population:** age 60+ with a PD diagnosis or neurodegenerative parkinsonism diagnosis (includes: progressive supranuclear palsy, multiple system atrophy, cortical basal degeneration, vascular parkinsonism, dementia with Lewy bodies)
- **Key study criteria**
  - 60 years and older
  - Not confined to bed or wheel chair
  - Must be able to walk without the assistance of another person
  - No history of hip fracture
- **This is entirely a home-based study, but our center is making referrals**
- **Study duration:** One-time infusion (home visit) and follow-ups every 4 months for 5 years
- **Drug administration:** a single intravenous infusion of either Zoledronic acid (ZA, 5mg) or placebo, infused over 45 minutes, given at home
- **Current study status: ACTIVE, ENROLLING**

8) Title: PD GENEration (PD GENE)

- **Sponsor:** Parkinson's Foundation
- **PI:** David Simon
- **Coordinator:** Áine Russell, arussel2@bidmc.harvard.edu, 617-667-9885
- **Main goal:** This is a genetic testing initiative to create a sample repository for PD-specific genetic information for future research use.
- **Study population:** people diagnosed with PD
- **Key study criteria**
  - Over the age of 18
- The genes covered in this panel include: LRRK2, GBA, PRKN, PINK-1, PARK7, SNCA and VPS35
- **Administration:** The PF will mail a buccal swab kit directly to the patient's home.
- **Current study status: ACTIVE, ENROLLING**