Celecoxib versus placebo as an adjunct to treatment-as-usual in children and youth with obsessive-compulsive disorder: A single-site randomized quadruple-blind phase II study

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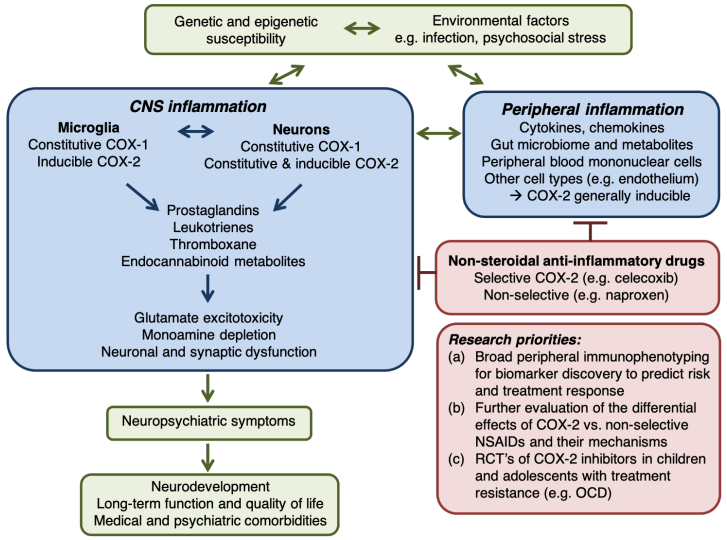
Background

- Clinical and epidemiological studies suggest an association between childhood-onset OCD and altered immune function/inflammatory events.
- Clinical practice guidelines suggest non-steroidal anti-inflammatory drugs such as cyclooxygenase (COX) inhibitors as third-line adjunctive therapy in adults with OCD and in children with pediatric acute-onset neuropsychiatric syndrome (PANS) and pediatric autoimmune neuropsychiatric disorder associated with streptococcal infections (PANDAS), but there is limited empiric evidence for this approach.
- COX enzymes oxidize arachidonic acid to prostaglandins, which modulate neuronal function and inflammation in the central nervous system. Pre-clinical studies and preliminary data in adults suggest that COX-2 inhibition can modulate mood and anxiety symptoms.



Primary Objective

To determine the efficacy of the COX-2-selective inhibitor celecoxib as an adjunct to treatment-as-usual in children and youth aged 7-18 with moderate-to-severe OCD.

Overview of Methods

- Phase II single-centre superiority trial
- Two parallel groups: celecoxib 100 mg twice daily and placebo
- Participant, care provider, investigator, and outcomes assessor are blinded/masked to treatment assignment
- Randomized 1:1 allocation with random block size, stratified by baseline symptom severity (CYBOCS score 16-23 vs. ≥24)
- Target recruitment is 80 participants (40 per arm)
- The primary outcome is OCD severity (as measured by total CY-BOCS score) after 12 weeks in the celecoxib compared to placebo arm, adjusted for baseline OCD severity
- Participants will be invited to participate in ancillary studies including blood/saliva/stool collection for future biomarker analyses.
- Refer to Clinicaltrials.gov (NCT04673578) for more details.

Key eligibility criteria

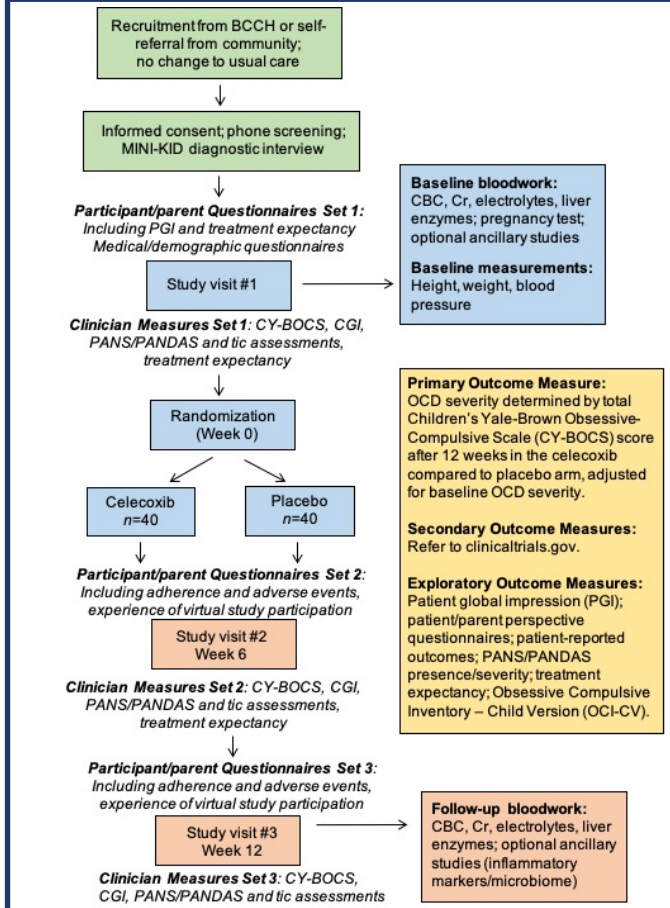
- DSM-5 diagnosis of OCD based on prior clinician assessment and standardized diagnostic MINI-KID interview
- CY-BOCS score of ≥16 (moderate –to-severe OCD)
- No treatment changes in past 4 weeks or during study period
- Parent / legal guardian with capacity to provide informed consent

Summary

The Adjuctive CElecoxib in Childhood-Onset OCD (ACE-OCD) study will be the first to assess the efficacy and safety of adjunctive celecoxib in pediatric OCD. It has been approved by the UBC C&W Research Ethics Board and a No Objection Letter has been received from Health Canada.

This study is currently open to recruitment.

Study visits and assessments



Funding and contact

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