**Participant Information and Assent Form (Ages 14-18)**

**Adjunctive CElecoxib in childhood-onset OCD (ACE-OCD) study**

**Who is in charge of this study?**

The doctor in charge of this study is **Dr. Evelyn Stewart**. She is being helped by other doctors at BC Children’s Hospital and by members of the Provincial OCD Program. If I need to talk to someone or have any questions, I can call Boyee Lin or Cynthia Lu at **(604) 875-2000 (ext. 3068)** or email them at aceocd@bcchr.ca. If I am having problems or there is an emergency and I cannot talk to my parents I can also call the doctors at **604-809-6622** (Dr. Stewart) or **778-837-4946** (Dr. Westwell-Roper).

**Invitation**

I am being invited to take part in this research study because I have been diagnosed with obsessive compulsive disorder (OCD). This study tries to find out whether a drug called celecoxib can help treat OCD in children. The following pages explain the study so that I can decide if I want to take part or not. It is up to me if I want to be in this study. No one will make me be part of the study and no one will be mad at me if I choose not to be part of this study.

**Do I have to be in this study?**

I do not have to participate in this study if I don’t want to. If I choose to participate, I can stop being in it at any time. If I see a doctor or other health care provider for treatment of my OCD, they will continue to take care of me as they have in the past, regardless of whether I am in the study or not.

If I want to participate in this study, I will be asked to sign this form. My parent/guardian will need to sign a consent form before I am enrolled in the study; but I do not have to participate even if they sign the consent form. The researchers will not enroll me into the study unless I agree to do so.

I should read the following information carefully and discuss it with my family, and if I wish, my doctor, before I decide. I understand that I should feel free to talk to the study doctors if anything below is not clear. I can choose to be in the study, not be in the study, or take more time to decide. Even if I agree now to be part of the study, I can change my mind later. I can ask the study doctor or study coordinator any questions I may have at any time during my study participation.

**Why are we doing this study?**

I have a condition called OCD. Children who have OCD often have upsetting thoughts or feelings (obsessions) that become so big that they make them do things they do not want to do (compulsions). Because of these obsessions and compulsions, kids often have difficulty doing fun and important things, like playing with friends and going out with family. Even though completing certain actions makes them feel better for a while, the upsetting thoughts and feelings keep on coming back.

This study will help researchers figure out whether a drug called celecoxib (a type of medication also used for pain, like ibuprofen or Advil) can help children with OCD. It will be added to any regular treatments that participants are receiving. It has been tested in adults with OCD and in children with other medical conditions, but not in children with OCD. Sometimes doctors use it or a related medication for children with OCD, but they do not know how well it works.

In order for the researchers to better understand how well celecoxib really works, some participants will receive a placebo instead of celecoxib. A placebo is an inactive substance, which means that it will not have an effect on my brain or body. It looks identical to celecoxib but will not have any medication in it. The decision of whether I receive placebo or celecoxib will be made at random by a computer program (similar to tossing a coin). Neither I nor the study doctors and nurses will be aware of whether I am receiving celecoxib or placebo. After 12 weeks, I will have the option to complete an additional 12 weeks of treatment during which we will know that I am receiving celecoxib.

**Why am I being invited to be in this study?**

I am being invited to be in this study to test if celecoxib will reduce OCD symptoms over a period of 12 weeks in patients who have OCD like me. In total, 80 participants are expected to take part in this study.

**What will happen to me in this study?**

**Overall design**

During this study treatment, my usual treatment (medications and/or psychotherapy that are standard therapy) should not change during the study and should be monitored by my regular treating doctor (s). The study procedures and treatment described below are in addition to this standard therapy. If I am interested in participating in this study, I can expect:

***Screening:***I will participate in a screening interview phone call together between my parents and Research Assistant to answer questions about my health and to see if I am eligible for the study. If I am, then my parents and I will go to see a study doctor (at BC Children’s Hospital or on the computer using videoconference) to assess my OCD severity, and ask about symptoms of PANS/PANDAS and tics. Before the visit with the doctor, my parents and I will answer some questions about my health, demographic, and perspective on the computer. After the visit, blood work would be needed for some tests to make sure it is safe for me to take the medication in this study. My height, weight, and blood pressure will also be measured. If the conditions show that I am not suitable to participate in the study, I will not proceed to randomization or treatment in this study but will be referred for further assessment and treatment to my regular doctor or primary care provider.

At the first study visit, I will also be able to discuss the study treatment, procedures, and potential risks and benefits further with a study doctor. Any questions I have about the treatment, potential side effects, and alternatives will again be addressed.

***Randomization:***The study has two arms: participants will be split into 2 groups to receive either celecoxib or placebo capsules for a total of 12 weeks. Randomization is like the flip of a coin so that there is an equal chance of being in any of the groups. Therefore, when I receive the treatment, I will not know whether this medication is celecoxib or placebo. The study will also be quadruple blinded – participants (as well as doctors/care providers, study investigators, and team members assessing outcomes) will not know which group I am in. However, this information is available in case of an emergency.

Once the results of the blood work and height/weight/blood pressure measurements have been reviewed by a study doctor to see if I am eligible to receive treatment, I will be randomized to either celecoxib or placebo. These capsules will be dispensed by the BCCH Research Pharmacy and will be either picked up by me or delivered to my home, depending on my location and preference. Participants 25 kg and under will receive capsules containing celecoxib 50 mg twice daily; those over 25 kg will receive 100 mg twice daily. Placebo capsules will appear identical and contain only non-medicinal ingredients. The capsule should be taken with food (ideally breakfast and dinner) and may be swallowed whole or sprinkled on moist food such as applesauce. The entire contents of the capsule should be consumed.

My parents will be asked to inform the study team of the date/time of my first dose, and to enter this as well as my preferred medication form (capsule or sprinkles) in an electronic participant diary. I will continue to use this diary to record concerns about side effects or any missed doses for the duration of the study. No changes will be made to my usual treatment or regular medical care.

***Study visits:***After beginning treatment, there will be two additional study visits after 6 and 12 weeks. Treatment and study participation will end at the 12-week visit. This study is designed to allow for study visits at BCCH in person only if it is safe to do so (according to current health authority and BCCH COVID-19 guidelines) and if this is preferred by me and my parents. Alternatively, study visits will take place remotely using the videoconferencing platform Zoom.

For the study visits, my parents and I will complete online questionnaires prior to these visits; these will take approximately 40 minutes each and include reporting of missed doses, potential side effects, symptom severity, and perspectives on study participation. At the study visit, I will meet with a Research Assistant and a study doctor. My parents and I will again be asked about my symptoms. The doctor will complete several standardized measures of symptom severity, which are listed in Table 1. After the 12-week visit, another blood work would be needed to make sure my body hasn’t reacted poorly to the medication.

***Duration of the study:***The screening process may take up to 4 weeks to allow scheduling of the telephone screening interview, first study visit, blood work, and height/weight/blood pressure measurements at my convenience, and to allow study doctors to review the results. Following randomization to celecoxib or placebo, I will receive treatment for 12 weeks. The maximum study duration is therefore 16 weeks or approximately 4 months. The estimated time required for each study component is included in Table 1. In addition, there is an option to complete a 12-week “open-label” phase with celecoxib treatment at the end of this period.

***Questionnaires and interviews:***This study involves multiple questionnaires and interviews, listed in Table 1. In addition to the screening interview and study visits at which I will answer questions, my parents and I will complete online questionnaires prior to and following each visit. I do not need to answer questions that I am not comfortable answering, and may take breaks from questionnaires or interviews at any time.

**Table 1.** Schedule of study visits and procedures

|  |  |  |  |
| --- | --- | --- | --- |
| **TIMEPOINT (weeks of treatment)** | -4 to -1  | 6  | 12  |
| **Study Visit****or Procedure** | Screening | 1 | 2 | 3 |
| **ENROLLMENT(phone interview; approx. 60 min total):** |
| Pre-screening consent | x |  |  |  |
| Review of inclusion/exclusion criteria | x |  |  |  |
| Informed consent form review  | x |  x | As needed |
| Diagnostic interview | x |  |  |  |
| **ADDITIONAL SCREENING ASSESSMENTS (60 min total):** |
| Medical and demographics questionnaires (Online, 20 min, prior to visit) |  | x |  |  |
| Height, weight, blood pressure, heart rate (10 min, at or following visit) |  | x |  |  |
| Blood work: CBC, AST, ALT, Cr, electrolytes, (pregnancy test – visit 1)(30 min, following visit) |  | x |  | x |
| Blood collection for BioBank (optional, with other blood work following visit) |  | x |  |  |
| **INTERVENTIONS:** |
| Pharmacy: Randomization and dispensing (following Visit 1 and all screening assessments)  |  | x  |   |   |
| Celecoxib (weeks 0-12)  |  |   |   |   |
| Placebo (weeks 0-12)  |  |  |  |  |
| **PARTICIPANT-/PARENT-REPORTED MEASURES (120 min total):** |
| Participant perspective questionnaire (Online, 30 min, prior to visit) |  | x | x | x |
| Adverse event monitoring questionnaire (Online, 20 min, prior to visit) |  |   |  x | x  |
| Adherence assessment (Online, 5 min, prior to visit) |  |  | x | x |
| Participant electronic diary (Adverse events, missed doses) |  | As needed |
| **CLINICIAN-REPORTED MEASURES (completed at study visit, each 30-60 min = 90-180 min total):** |
| OCD symptom severity (CY-BOCS; Clinician Global Impression of Improvement and Severity) |  | x | x | x |
| PANS/PANDAS and tic symptom assessments |  | x | x | x |
| Treatment expectancy |  | x | x | x |
| **TOTAL TIME PER VISIT (min):** | ~60  | 120-150 | 85-115 | 85-115 |
| **TOTAL PARTICIPANT/PARENT TIME:** | 330-420 min (5-7 hours) + additional time to take drug twice daily and complete electronic diaryas needed |

**Can anything bad happen?**

Sometimes medications can cause side effects, which can make people feel sick. The doctors do not know very much about how celecoxib might work in children with OCD. But they do know that some children who have taken celecoxib for other reasons have stomach aches, nausea, or diarrhea, especially if they do not take the medication with food. Some of the more common possible side effects of celecoxib when given to adults were abdominal pain (4 in 100), diarrhea (6 in 100), stomach ache (9 in 100), nausea (4 in 100), headache (16 in 100), and cold symptoms (8 in 100), but many adults taking placebo also reported these symptoms.

If I feel sick or if I notice any strange or bad feelings during the study, especially if they are unexpected or severe, I will let my parents or doctors know right away. I can call one of the study doctors: Dr. Stewart at **604-809-6622** or Dr. Westwell-Roper at **778-837-4946**. I can call at any time, day or night, to tell them about how I feel. During the day, I can call the study members Boyee Lin or Cynthia Lu, at **(604) 875-2000 (ext. 3068)** or email them at **aceocd@bcchr.ca.**

I will also have to answer some questionnaires during this study. I may feel uncomfortable when I am asked questions that are hard to answer, but I am allowed to not answer any questions without explaining why. I may be nervous about doing the treatment or seeing the doctor. My parent(s) will be there to help me and I will not have to do anything that I do not agree to do.

**For girls: Are there risks if I get pregnant?**

It is not very well known how celecoxib will affect a pregnancy or the developing baby, but it may cause harm especially later in pregnancy. If I am getting my menstrual periods and am sexually active, I must use a study-approved birth control method and agree to try not to get pregnant during the study. It is important that I contact my doctors right away if I think I may be pregnant, if I have missed a period or it is late, or I have a change in my usual menstrual cycle (for example, heavier or lighter bleeding than usual, or bleeding between periods).

It is not expected that taking celecoxib would increase the risk to a baby if the father took celecoxib before or around the time it was conceived.

**Could I get better by being in this study?**

No one knows whether or not I will get better by being in this study, and I may get worse. The study doctors hope that I will get better, but they cannot tell me that I will get better. By participating in this study, the doctors hope I may learn more about my OCD and that the information learned from this study can be used in the future to benefit other people with OCD.

**Are there any other treatments for me?**

If I am already receiving treatment for OCD, I will continue to receive it during this study from my regular physician or other health care provider. I do not have to be a part of this study to continue receiving any other treatments that are available. I can ask my regular doctor, study doctor, or my parents about other treatments and therapies.

**Who will know I am in this study?**

Only my doctors and people who are involved in the study will know I am in it. My information will be kept private. When the study is finished, the doctors will write a report about what was learned. This report will not say my name or that I was in the study. My parents and I do not have to tell anyone I am in the study if we don’t want to.

My privacy will be respected. To participate, I must allow the study team to communicate information regarding my medical condition and safety to at least one of my regular doctor(s). Unless I allow them to, the study team will not tell anybody else I am or have been a part of this study. They will not release any information to anybody else that could be used to identify me, unless they are required to do so by law. For example, researchers are required to report if a participant is believed to be at risk for harming him/herself or others.

In order to protect my privacy, the study team will remove any information that may be used to identify me from any study documents, and instead of my name appearing on them, I will be identified by a specific study code number that applies only to me. Only this code number will be used on any research-related information collected about me for this study, so that my identity as part of the study will be kept completely private. Only Dr. Stewart and her research assistants will have the ability to link this code number with my personal information, and the linking information will be kept in a locked office and cabinet on the third floor of the BC Children’s Hospital Research Institute under the supervision and control of Dr. Stewart.

There may be times when information about me may be made known if I am in danger to others or myself, as decided by the study doctor. The study doctor could contact 911 (if there is a concern for harm likely to occur at any moment), contact a child welfare worker (if there is a concern about my safety in the home or in need for protection), or refer me and my family to the nearest emergency department.

If I am unable to meet face to face with people involved in the study or don’t want to, I can meet them online on a program called Zoom. Even though there is a chance that health information might be seen or accidentally be sent, the research team has done several things to keep my identity safe. These include using a version of Zoom that belongs to the university or the hospital, that joining Zoom needs a code that I will know before the meeting, that the link to the Zoom will be known only by people involved in the study, me, and/or my family, and the session will not be recorded. I will also be asked some questions about the answers I gave in the study to make sure it’s really me when meeting on Zoom. I will also be asked where I am in case of an emergency, while the study doctor will also tell me where he/she is. The study team will also go through with me of times when information about me may be made known.

I should use a nickname or a fake name, and not my real name, when joining Zoom. If I want, I can also turn off my camera and microphone. But there will be times I will be asked to turn on my camera and/or microphone by the research staff on Zoom to make sure of the data that I am giving.

**What will the study cost me?**

All research-related medical care and treatment and any related tests that I will receive during my participation in this study will be provided at no cost to me.

My family may have to cover costs related to travel and parking for sessions held at the hospital, such as the study visits. As a result, my family will receive an $25 gift card for the first and second visits and a $50 gift card for the final visit of the whole trial in order to cover these expenses. I will also receive a letter of recognition for the voluntary time I have contributed to the research study. The letter will not contain any information regarding diagnosis.

**Who do I contact if I have questions about the study during my participation?**

If I have any questions or desire further information about this study before or during participation, or if I experience any side effects that were not outlined in this assent form, I can contact Boyee Lin or Cynthia Lu at **604-875-2000 (ext. 3068)** or email them at **aceocd@bcchr.ca.**

**Who do I contact if I have any questions or concerns about my rights as a participant?**

If I have any concerns or complaints about my rights as a research participant and/or my experiences while participating in this study, I should contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). I should reference the study number (H19-03886) when contacting the Complaint Line so the staff can better assist me.

**FUTURE STUDIES**

There is a chance that during or after this study the study team will find other questions needing answers that require future studies. If I am willing to hear about these future studies, I will mark the “yes” box. This does not mean that I will have to take part in a new study, just that the study team will let me know about it. If I do not want to be contacted about new studies, I will mark the “no” box.”

**Am I willing to be contacted by the researchers for future studies?**

**YES** **[ ]**

**NO [ ]**

# **ASSENT TO PARTICIPATE**

# **SIGNATURE**

**Participant Assent**

My signature on this assent form means:

* I have read and understood this adolescent information and assent form.
* I have had enough time to consider the information provided and to ask for advice if necessary.
* I have had the opportunity to ask questions and have had acceptable answers to my questions.
* I understand that all of the information collected will be kept confidential and that the results will only be used for scientific objectives.
* I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing the quality of care that I receive.
* I understand that I can continue to ask questions, at any time, regarding my participation in the study.
* I understand that if I put my name at the end of this form, it means that I agree to be in this study.
* I agree to sharing of information required for safe medical or mental health follow-up with my primary or usual care provider.

I will receive a signed copy of this assent form for my own records.

I agree to participate in this study.

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Participant’s Signature Printed Name Date