The CANADIAN ARTHRITIS COHORT (CATCH): A Prospective Cohort Study of Adults with New-Onset Inflammatory Arthritis Symptoms

Investigators:
Principal Investigator: Vivian Bykerk, MD

Sponsor
This study is funded through [insert catch study sponsorship statement for current year here].

You are being asked to take part in a research study. Before agreeing to participate in this study, it is important that you read and understand the following description of the study. You do not have to participate in the study if you do not wish to. If you do participate, you can withdraw from the study at any time. Please ask the study staff or your rheumatologist to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction.

Why are we doing this study?
Rheumatoid arthritis is a chronic disease that can lead to disability and deformity. There is now convincing evidence of better outcomes for patients with inflammatory arthritis, who are diagnosed and treated within a few weeks of onset of their symptoms. Although we know that early treatment is important, we still don't know if there are factors that can predict how an individual patient's disease will progress and who will respond to various therapies. We are doing this study to describe patients with inflammatory arthritis at the onset of the disease. We would like to identify and understand the factors that can predict how a patient's disease might progress and their response to treatment. Furthermore, we would like to determine the proportion of patients with new-onset inflammatory joint symptoms who will go on to meet the diagnostic criteria for rheumatoid arthritis, and describe the best treatment strategies for patients who do not meet diagnostic criteria for rheumatoid arthritis but demonstrate similar symptoms.

Finally, there is recent evidence of inherited factors (genes) that are associated with an increased risk for RA. These genetic factors have not been identified. It is the aim of this study to determine the best care for patients by identifying genetic and protein factors that may impact on disease progression and treatment decisions in order to better define their roles.

What do I have to do?
As a patient with new-onset inflammatory arthritis symptoms attending an Early Arthritis Clinic, you are being asked to participate in a long term study, which will assess your disease activity, your blood results and the long-term outcomes of early rheumatoid arthritis and related conditions, if any.

Information collected during your regular visits to the Early Arthritis Clinic will be used for this study. This includes assessment of you by the physician and/or study nurse and blood tests every 3 to 6 months, as well as completion of family history and quality of life questionnaires. One of the blood tests will be used to determine some genetic and protein factors associated with

rheumatoid arthritis**. This blood is optional and you will be asked to sign a separate consent form for this.** X-rays of your hands and feet will be taken every 6 months for the first year and then annually or as clinically indicated. A chest x-ray will be done at baseline. This information will be collected during your regular clinic visits as part of regular care, regardless of whether you participate in the study.

If you agree to participate and have signed this consent form, you are allowing the investigators to use the routinely collected information for research purposes.

Will my information be kept confidential?
We have taken a number of steps to make sure that your information is kept secure and confidential. Information about how you feel will be collected by using a computer in the doctor's office. By collecting your personal medical information on a computer, instead of paper, we are using the most secure way to make sure your information is kept safe. A number, instead of your name, will identify all computer research records. All of the information about you will remain anonymous when it is sent to the main computer for storage. This way the data that is being collected for this study is following the rules of the Personal Health Information Privacy Act (PHIPA). Only the study investigators and the clinical research team of the Early Arthritis Clinic will have access to the coding list with your name on it.

This research data may be presented at conferences, seminars, or other public forums, and will be used for publications, but no identifiers will be included so as to ensure participant confidentiality.

How will my information be used?
Your information will be used to provide a description of the participants in this study. We will evaluate how people's disease changes over time and their response to treatment. Only summary information without any identifiers will be reported and published. These reports will be made available to the scientific community through publications and presentations.

Will this benefit me?
This study will not benefit you directly but it will help in developing better ways to treat patients with new onset inflammatory arthritis, thereby improving care for other patients in the future with your disease.

Alternatives
You may choose to attend the Early Arthritis Program, which is part of standard care and not participate in this study.

Is there any risk to participating in this study?
With the exception of the genetic testing, all information collected is part of your regular clinical follow-up.

Participation

Your participation in this study is voluntary. You can choose not to participate and you may withdraw from the study at any time without affecting your medical care. Participating in this study will not affect your clinical care.

Compensation
There is no monetary compensation for participation in this study.

Questions

You are urged to discuss any questions you may have about this study with the Early Arthritis Clinic staff members who will explain it to you. If you have further questions, you may contact the study principal investigator, Dr. Vivian Bykerk at [insert contact info]. If you have any questions about your rights as a research subject, you may call [insert Research Ethics Board Chair name and contact information].

Consent

I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I agree to allow the investigators to use clinical, laboratory, x-ray and questionnaire information collected during my regular early arthritis clinic visits for this long-term research study. I understand that my participation in this study is voluntary and I may withdraw at any time without affecting my care.

I will receive a copy of this consent form. In no way does this consent waive my legal rights nor release the investigators or involved institution from their legal or professional responsibilities.

_____	_____	_____
Patient's Name (Please Print)	Patient's Signature	Date

I confirm that I have explained the nature and purpose of the study to the subject named above. I have answered all questions.

_____	_____	_____
Name of Person Obtaining Consent	Signature	Date