UNIVERSITY OF ALBERTA

Information Sheet

RxIALTA: Pharmacist CVD Intervention for Patients with Diagnosed Inflammatory Arthritis

Principal Investigator(s):

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Background:
Cardiovascular disease (CVD) (disease of the heart and blood vessels) is one of the leading causes of death and disability in Canada today. The majority of CVD cases are caused by factors that can be controlled. These factors include tobacco use, obesity, high blood pressure, high cholesterol, diabetes, and physical inactivity. Such factors are common and not well controlled. Inflammatory arthritis (IA) (Inflammation of the joints and other tissues) is considered another risk factor or CVD. As such, people who have IA and any of the previously mentioned risk factors would be at high risk for developing CVD. Controlling these factors will bring down the risk of having cardiovascular disease and make the quality of the individuals' life better. Pharmacists work with patients and their family doctors to provide cardiovascular care. Having a pharmacist involved in the care process may help patients with IA reduce their CV risk. Pharmacists are easier to reach and may have more opportunities to educate people about medications. This might lead to better prevention and control of cardiovascular diseases.

Purpose:
You are being asked to participate in a research study to find out if pharmacist assessment and management of CV risk factors in patients with inflammatory arthritis will reduce their CV risk.

Procedures:
If you have inflammatory arthritis (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, gout, lupus, psoriasis) and have at least one of the following: elevated blood pressure, elevated blood sugar, elevated cholesterol or consume tobacco products, you will be asked to take part in the study. If you agree to take part in the study your pharmacist will review your history (medical, family and social [e.g. tobacco use]), medications and conduct an assessment that may include blood pressure, waist circumference, height and weight measurements. Pharmacists will also assess your most recent laboratory test(s) for cholesterol, three-month sugar control test (hemoglobin A1C), and kidney function (creatinine, estimated glomerular filtration rate (eGFR), random urine albumin to creatinine ratio) by accessing the provincial electronic health records (Netcare). If these laboratory results are not available, the pharmacist will give you a laboratory requisition form to do the tests without any extra cost to you and with a copy of the test sent to your family doctor.

Your pharmacist will enter the information into a computer program in order to calculate your risk of having a heart attack or a stroke. This computer program is interactive, where your pharmacist can show you the factors that are contributing to your risk and the extent of each contribution. It will also show you how controlling such factor(s) (eg. high blood pressure, high cholesterol, high blood sugar, or tobacco use) can reduce your risk. You and your pharmacist will come up with a plan for how to try to lower your cardiovascular risk. The plan may include medication changes or additions, tobacco cessation and lifestyle (healthy diet and exercise) support. Your pharmacist will discuss this plan with your family doctor

As part of being in the study, you will be asked to meet with your pharmacist every month for 6 months. (You may meet with the pharmacist more frequently if he/she deemed it clinically important). These meetings will usually last 10-20 minutes and can occur in person or over the

phone. During these meetings, your pharmacist will conduct assessments that may include blood pressure, waist circumference, height and weight measurements and talk to you about your cardiovascular risk, medications, diet, physical activity and tobacco cessation plan (where appropriate) and provide motivation. To help achieve your goals, the pharmacist may also order laboratory test(s) (eg. hemoglobin A1C, cholesterol); adjust or add medications; or refer you to other health care providers (family physician, rheumatologist) for support.

During this study, you will have close follow-up with both your pharmacist and your family doctor. Your family doctor will receive a letter from the pharmacist to let him/her know that you agreed to participate in this study. The letter will also contain detailed information of what the study is about. The pharmacist will let your family doctor know about the results of all the tests taken and any changes in your medications.

As part of being in this study, you will also be asked to complete a patient satisfaction survey. You will be given a survey that should take no longer than 5-10 minutes to complete. You may complete the survey in your pharmacy and place it in a sealed envelope or do it at home and mail it in. All surveys will come with a pre-paid postage envelope so they may be mailed with no cost to you.

Possible Benefits:
This pharmacist delivered program may help you to reduce your risk of having a heart disease or stroke by:

- Bring down your blood pressure
- Bring down your blood sugar
- Bring down your cholesterol level
- Quit tobacco

We hope that this study will show pharmacists ability to help the patient with IA manage their heart disease and stroke risks. This study will help us understand how pharmacists can help to prevent and manage cardiovascular disease in patients with IA.

Possible Risks:
Your medications may be changed or altered in dose to help you bring down your cardiovascular risk. These changes and alterations may cause side effects such as dizziness, muscle pain, headaches, and stomach pain. Increasing the drugs doses or frequency may increase the cost of your treatment if you do not have health insurance (private or governmental). Also, you would be asked to do some laboratory tests, those tests will require a blood sample, obtaining this sample may be painful and may cause bruising at the site.

Your pharmacist will help you to understand your medical condition. The pharmacists will work with you and your family physician to help you quit tobacco, bring down your blood pressure, cholesterol level, blood sugar and encourage you to make healthier lifestyle choices.

Your cardiovascular risk may not be brought down even by the end of the study.

You will also continue to receive usual care from your family doctor for all your medical conditions.

Confidentiality:
The data collected for this study will be kept strictly confidential. It will not be released unless we are required to do so by law. Your name will not be revealed outside the research office, which is in a secure area. No information that could identify you will be included in any report published

from the study. The University of Alberta requires us to keep data from the study for five years. Even if you withdraw from the study, your data will not be destroyed. The Health Research Ethics Board has authorized us to use the data for this study only. Any future use of the data requires additional ethics approval.

By signing the consent form you give permission to study staff to access the necessary personal information from other health care professionals (like your family doctor). Specifically, we will obtain from your pharmacist information on your prescribed medications and laboratory test results.

Voluntary Participation

You do not have to take part in the study at all, and you can quit at any time. If you decide not to participate in the study or if it is stopped at any time, the quality of your care will not be affected. If we find anything out, which may affect your decision to continue in the study we will inform you as soon as possible.

Reimbursement of Expenses

You will not be paid for participating in this study.

Contact Names and Telephone Numbers

If you have any concerns about any aspect of this study, you are encouraged to contact the University of Alberta Health Research Ethics Board at (780) 492-2615. This office is not connected with the researchers setting up this study. You may also contact Dr. Ross Tsuyuki, Dept. of Medicine: (780) 492-8526 or Dr. Yazid Al Hamarneh, Dept. of Medicine: (780) 492-9608 or 1-877-876-9888.

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CONSENT FORM

RxIALTA: Pharmacist CVD Intervention for Patients with Diagnosed Inflammatory Arthritis

Principal Investigators: Dr. Ross Tsuyuki 780-492-8526

Dr. Yazid Al Hamarneh 780-492-9608

	Yes	No
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to your records, including personally identifiable health information?	☐	☐
Do you agree to allow the investigators to contact you about future studies?	☐	☐

Who explained this study to you? _____

I agree to take part in this study: YES ☐ NO ☐

Signature _____

(Printed Name) _____

Date:_____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Person Obtaining Consent _____ Date _____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT