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New anticoagulants for stroke prevention in patients with atrial fibrillation and prior intracerebral hemorrhage (NASPAF-ICH)

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a) Statement of health problem or issue:

An abnormal heartbeat that causes blood clots (atrial fibrillation [AF]) affects 2-3% of Canadians. Strokes from this condition are often very serious and can cause death. Fortunately, strong blood thinners are very helpful in preventing stroke in this situation. But, worry amongst doctors for bleeding while on these drugs has led to low levels of use of these life saving drugs. Using these blood thinners in persons with AF and previous bleeding in the brain is of major concern. It requires balancing the benefit of preventing stroke against the higher chance of another bleed. As these drugs have never been tested properly in patients with previous bleeding in the brain, there currently exist a lot of different practices depending on the doctor. Often doctors choose to treat with aspirin in this situation because they believe it to be safer, but aspirin is not ideal for preventing strokes from AF. These different practices without proper evidence put patients at risk for harm.

b) Objective of your program:

New blood thinners (non-vitamin K oral anticoagulants) are now available. These drugs are proven to prevent stroke from AF well and have very low risk of bleeding in the brain when compared to older drugs. The low levels of bleeding are similar to that of aspirin. We will assess the safety of new blood thinners, for the first time, in patients with AF who are at high risk for stroke and prior bleeding in the brain. Our goal is to eventually show the safety and benefit of these blood thinners for stroke prevention in such patients. The information obtained from this initial smaller study will be then be used to design and complete a larger global research project to confidently answer this question.

c) How will you undertake your work?

We will run our research study at 15 hospitals with expertise in stroke across Canada. Patients who have AF with a high risk for stroke and previous bleeding in the brain will be asked to participate. Participants will be designated randomly to take either a new blood thinner or aspirin. Our goal is to recruit

150 patients over two years and follow them for an average of one year. During this time we will monitor blood pressure and the number of bleeding events in both groups to ensure safety. At the end of the study we will compare the number of strokes and recurrent bleeding in the brain between patients on aspirin and those on new blood thinners.



d) What is unique/innovative about your program?

This is the first study assessing the safety of new blood thinners in persons with previous bleeding in the brain. It is also the first to properly test stroke prevention drugs in patients with AF and previous bleeding in the brain.

e) How is the proposed research directly relevant to heart disease and/or stroke?

Our study is assessing the best way to prevent stroke in people who have a common form of heart disease (AF) and bleeding in the brain.



f) What is the impact of the proposed research to heart disease and/or stroke?

Clinical guidelines currently do not provide firm recommendations on the use of blood thinners in patients with AF and prior bleeding in the brain. This is due to the lack of existing evidence to guide practice. As a result, doctors currently don't know the best way to treat these patients and there are a lot of different approaches currently in use. These different approaches are likely exposing patients to harm from inadequate stroke prevention. The successful completion of our research program will offer the required evidence to provide firm cardiology and stroke guidelines on the matter. This will directly improve the quality of care and life of patients with stroke and heart disease.