IMPROVE (Identifying Methods for Postpartum Reduction of Vascular Events): Pilot Randomized Controlled Trial

INFORMED CONSENT FORM

SEPTEMBER 25, 2017

TITLE: IMPROVE (Identifying Methods for Postpartum Reduction of Vascular Events) Pilot Randomized Controlled Trial

SPONSOR: University of Calgary

INVESTIGATORS: Dr. Kara Nerenberg (403) 220-6376, kara.nerenberg@ucalgary.ca

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

BACKGROUND

Pregnancy is a window to a woman's future cardiovascular (CV) health. Many common disorders related to pregnancy can predict a woman's future CV health and CV risk. Hypertensive disorders of pregnancy (HDP) include preeclampsia, eclampsia, and gestational hypertension. Women with HDP are at higher risk for cardiovascular disease (CVD) and death. They experience CVD at an earlier age than average. They also have a lower survival rate than women with uncomplicated pregnancies.

To achieve CVD health targets set out by the American Heart Association, healthy lifestyle modifications are suggested as first-line therapy. Taking medication is second-line therapy. There is little research that assesses the short-term or long-term effectiveness of lifestyle interventions in women with HDP.

This pilot study is the first one to assess the feasibility and effects of a one-year, postpartum specific CVD prevention lifestyle program in women with HDP. Women who consent to being part of the study will be randomized to either the intervention or control arm. This is like rolling a dice. It will be done using an online central randomization system. The research assistant in charge of outcome assessments will not know which arm each participant is in. The study statistician will not have this information either.

A total of 84 women will be enrolled at 1 centre.

WHAT IS THE PURPOSE OF THE STUDY?

The main purpose of this study is to assess whether it is feasible to carry out a postpartum CVD prevention lifestyle program in women with HDP. It is also to assess whether the Ottawa-based CardioPrevent® program can be used in a centre in Calgary. A smaller part of this study will include an evaluation of how effective this intervention is on clinical outcomes. It will also compare microvascular function between the two study arms.

WHAT WOULD I HAVE TO DO?

If you choose to participate in the study, you will be asked to:

- Attend three in-person appointments for clinic assessments: baseline (6-12 weeks postpartum), 6 months after baseline, and 12 months after baseline
- Have blood pressure, body composition, smoking status, medication use, metabolic syndrome, breastfeeding/infant feeding, cardiovascular risk, and microvascular function assessed at each appointment
- Have a fasting blood sample (collected after a minimum 8-hour fast) and a urine sample taken at each appointment
- Complete questionnaires on postpartum depression, diet, physical activity, satisfaction with patient-physician interactions, and social support
- Wear an accelerometer to track your physical activity
- Refrain from sharing your treatment arm with other participants in the study
- Refrain from sharing your treatment arm with researchers you interact with during the course of the study

If you are randomized to the intervention arm after the baseline visit, you will also be part of the CardioPrevent® Program. This program consists of 25 contacts with a trained lifestyle counsellor. During the baseline screening session with the counsellor, participants will receive a report of their risk factor profile along with risk factor goals. Educational modules have been developed to address specific lifestyle issues. Issues include quitting smoking, healthy eating, exercise, and weight management. Modules will be provided to participants as needed. For your convenience, most of these contacts will take place by phone. At least three; however, will take place in person (at baseline, 6 months, and 12 months). Your lifestyle counsellor will work with you to decide on a contact schedule that suits your needs. As much as possible, in-person contacts will be scheduled to take place in conjunction with the clinical assessments described above.

WHAT ARE THE RISKS?

There is no risk to taking part in the study. There may be some slight discomfort during the baseline, 6 month, and 12 month clinic assessments. This is due to fasting blood sample that will be drawn. Information you share during lifestyle counselling sessions (intervention arm only) will be kept private. All data will be presented in aggregate form so that no individual participant can be identified. You do not have to share any personal information that you do not want to.

WILL I BENEFIT IF I TAKE PART?

If you agree to participate in this study there may or may not be a direct benefit to you. The information we get from this study may help us to provide better treatments in the future for women with HDP.

DO I HAVE TO PARTICIPATE?

Your participation in this study is voluntary. You are free to choose to participate or not to participate in this research study. If you agree to participate in this study, you may choose to withdraw your participation at any time. This will not jeopardize your future health care in any way. You may also refuse to answer any specific questions. If new information becomes available that might affect your willingness to participate in the study, you will be informed as soon as possible.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

You will be reimbursed for parking/transit and childcare costs (if needed) for clinic visits you attend as part of the study.

WILL MY RECORDS BE KEPT PRIVATE?

All information obtained during the study will be kept private. It will only be accessed by the study team. Your name will not be linked to notes from the session. All information will be stored in a secured office and/or on a password-protected computer. Authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at your identifiable medical/clinical study records held at the University of Calgary for quality assurance purposes. No other information identifying you will be transferred outside the investigators in this study. Anonymized data may be used in future academic publications and conference presentations.

A description of this clinical trial will be available on www.clinicaltrials.gov as required by the U.S law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the University of Calgary, Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a participant. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

Dr. Kara Nerenberg (403) 220-6376

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

Participant's Name	Signature and Date
Investigator/Delegate's Name	Signature and Date
Witness' Name	Signature and Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.