Why are You Being Asked to Take Part in this Research?

Your doctor is interested in understanding whether certain high-risk pregnancies are associated with future development of cardiovascular disease or risk factors for cardiovascular disease.

In order to do so, your doctor is learning more about women who have uncomplicated pregnancies compared with women who have specific high-risk pregnancies. These high-risk pregnancies include pregnancies complicated by high blood pressure (hypertensive disorders of pregnancy), diabetes discovered during pregnancy (gestational diabetes), and placental abnormalities (problems with the organ in the uterus that feeds the growing baby during pregnancy).

Women with high-risk pregnancies may have a greater likelihood of developing traditional risk factors for cardiometabolic disease, such as obesity, high LDL ("bad") cholesterol, high triglycerides (high blood fat), low HDL ("good") cholesterol, high blood pressure, smoking, or physical inactivity.

Alternatively, they may have risk factors for future cardiometabolic disease that have not yet been identified and may be unique to women. Over time, women with these high-risk pregnancies may have a higher risk for developing "cardiometabolic diseases" such as heart attack, stroke, blockages in arteries throughout the body, and diabetes.

Better understanding the relationship between high-risk pregnancy and cardiometabolic diseases may help doctors to identify women who need to be followed more carefully after their pregnancies, and hopefully to prevent them from developing cardiovascular disease in the future.

How Many People Will Take Part in the Study?

Approximately 1,000 women may participate in this study.

Supported by:

Department of Cardiology
- Anjli Maroo, MD, FACC – Principal Investigator (PI)
- Praful V. Maroo, MD, FACC – Co-Investigator
- Wilson Tang, MD, FACC – Co-Investigator

Department of Obstetrics and Gynecology
- S. Jules Moodley, MD – Co-Investigator
- Yogesh Shah, MD – Co-Investigator

Community West Foundation
Illuminating Hope

PCOR is supported by the Community West Foundation. This study has been reviewed and approved by the Cleveland Clinic Institutional Review Board.

If you are interested in participating, contact:

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Pregnancy and Cardiovascular Outcomes Registry (PCOR)

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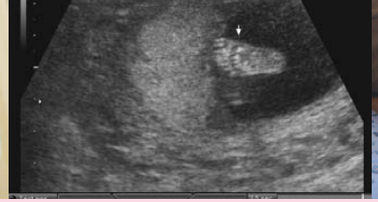




Why is this Study Being Done?

We are only beginning to understand the potential relationships between pregnancy and heart disease. Often, women who do have a high-risk pregnancy do not have regular follow-up to screen for cardiometabolic risk factors. Therefore, the opportunity to prevent the development of serious disease is missed.

This study is a registry study. A registry study gives doctors the opportunity to gather a large amount of information on a specific group of patients over an extended period of time.

The doctors and research assistants in this study are interested in determining whether women with high-risk pregnancies have a higher likelihood of developing cardiovascular disease or cardiometabolic risk factors after their pregnancies. This information may help doctors to better understand how cardio-metabolic disease develops in women. This may help doctors in earlier recognition of risk factors and provide an opportunity to manage certain risk factors before the condition worsens or a more serious event (such as a heart attack or stroke) occurs.

Are There Benefits to Taking Part in the Study?

Your participation in the study may generate information that benefits other women who may be at risk for future cardiovascular disease. Your participation may also help to identify risk factors for cardiometabolic disease that are unique to women. After pregnancy, your participation will provide you with a cardiovascular screen at regular intervals during the follow-up period.

If you have cardiometabolic risk factors that are identified during the course of the study, you will be notified for further treatment options that could potentially reduce your risk for developing more serious disease. However, you may not experience any personal benefit from participating in this research study.

You will receive no compensation either now or in the future for participating in this research project. The scientific information obtained in this research project can be used in other future research efforts. Such research may contribute directly or indirectly to the creation of new diagnostic tests, new medicines, or other events that may be commercially valuable.

You will not receive financial compensation in the event the results from this research lead to the development of new products.

What are the Risks of the Study?

Risks related to this study include those related to the blood draw.

What Other Options are There?

The alternative to participating in this registry is to not participate. If you choose not to participate in this study, you will continue to receive the same high standard of care provided by your doctor.

Will Your Information be Kept Private?

Absolutely. The information recorded about you as part of this research will be maintained in a confidential manner. The medical and research information will be used within Fairview Hospital, a Cleveland Clinic hospital, and/or disclosed outside Fairview Hospital as part of this research without any individual identifiers.

What are the Costs?

There will be no additional costs to you as a result of being in this study.

Enrollment Criteria

Interested women must be currently pregnant and at least 18 years old. The following types of pregnancies are eligible for enrollment:

- Normal pregnancy
- High-Risk pregnancy with at least one of the following diagnoses:
  - Gestational hypertension
  - Gestational diabetes
  - Pre-eclampsia
  - Eclampsia
  - Placental abruption
  - Placental infarction

What is Required for the PCOR Research Study?

Study subjects must be able to give voluntary informed consent and be willing to participate in a PCOR visit before delivery, after delivery and five follow-up cardiovascular visits over a nine-year period.

PCOR visit before Delivery

- Review and signing of PCOR consent form
- Completion of a medical questionnaire
- Blood Draw

PCOR visit within two days after delivery

- Completion of medical questionnaire
- Blood draw
- Placenta sample taken

PCOR-Follow-up Cardiovascular Visits one year after delivery and every two years after that

- Completion of medical questionnaire
- Blood draw
- Cardiovascular assessment to include cholesterol and glucose testing