Randomized Evaluation of Bromocriptine In Myocardial Recovery THerapy for Peripartum Cardiomyopathy

REBIRTH

Key Points for Research Participants

What is Peripartum Cardiomyopathy?

Peripartum cardiomyopathy (PPCM) is a rare form of heart failure that can happen between the last month of pregnancy and five months after giving birth. PPCM is a heart disease where the heart enlarges and the muscle weakens, resulting in less blood pushed out of the heart with each contraction. You may feel short of breath or tired when you are trying to move or exercise. Research suggests that family traits from your parents (known as your genes) and inflammation of the heart muscle can cause your heart to become weak. These factors may also be why you have PPCM. The overall cause of PPCM remains unknown.

What is the purpose of this study?

On heart failure medical therapy we have shown that the majority of patients recover except for those with weak hearts (ejection fraction ≤40%). In Europe, a drug called bromocriptine is used to further strengthen the heart but has not been studied in the US. The purpose of REBIRTH is to test whether bromocriptine can strengthen the heart when compared to those not taking the drug (inactive pill) while all remain on heart failure medication. Bromocriptine is approved by the United States Food and Drug Administration (FDA) to treat irregular periods and other symptoms that result from having high blood levels of prolactin (a protein normally high after pregnancy). It is not currently approved in US for PPCM.

Who is being asked to be in the study?

Women with a recent diagnosis of PPCM who are 18 years of age or older, within 5 months after delivery and not breastfeeding. Women who breastfeed may be eligible to be in group that does not take study drug.

What would I need to do to be in the study?

- First visit: In-person approximately 2-2.5 hours
- Follow up visits: In person at 1, 3, 6, and 12 months. When possible the follow up visits will be coordinated with your routine visits. When in person visits are not possible some of these follow up visits may be handled remotely
- Follow up visits at 24 and 36 months which can be done in person or remotely
- Take study drug for 8 weeks
- Duration of participation: Approximately 3 years
- Procedures during visits may include:
  - Clinical assessment
  - Medical history
  - Research blood draw for biomarkers done at 4 visits
  - Echocardiogram
  - Questionnaires
  - Study drug counts

REBIRTH For more information contact:_____ https://peripartumcmnetwork.pitt.edu